UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

CONSOLIDATED REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS' MOTIONS FOR PARTIAL SUMMARY ADJUDICATION WITH RESPECT TO THE CONTROLLED SUBSTANCES ACT (DKT. #1910-1 & #1924-1)

August 16, 2019

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INTRODUCTION

In their two summary judgment motions pertaining to suspicious order monitoring ("SOM"), Plaintiffs established the legal contours of Defendants' obligations under the Controlled Substances Act ("CSA") and provided sufficient evidence to establish, as a matter of law, that Defendants failed to comply with those obligations.[1] In response, Defendants attempt to dispute the scope of their legal duties and simultaneously (if somewhat paradoxically) establish their compliance.[2] Because Defendants discuss the legal and factual issues in their responses to both motions, for the convenience of the Court, Plaintiffs here provide a consolidated reply to both motions.

Defendants argue that the CSA and its implementing regulations do not impose any duties on registrants, much less a duty to halt opioid shipments pending a due diligence investigation to establish that diversion is unlikely. As a matter of statutory and regulatory construction, this argument is wrong: registrants are affirmatively required to maintain effective controls against diversion and there can be no effective controls if registrants are permitted to ship orders they know to be suspicious without first determining that the orders are unlikely to be diverted.[3] But the

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[1] *See* Memorandum in Support of Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties under the Controlled Substances Act ("Ps' Duties MOL"), Dkt. #1910-1; Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them [Second Corrected Brief] ("Ps' Compliance MOL"), Dkt. #1924-1. The exhibits to Ps' Compliance MOL will be referred to herein as "Ps' Ex. #." Additionally, Plaintiffs attach hereto Exhibits 521 - 606, which will be indicated in bold ("**Ps' Ex. #**") for the convenience of the Court.

[2] *See* Defendants' Opposition to Track One Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties under the Controlled Substances Act [Defs' CSA "Duties" Brief] ("Duties Opp."), Dkt. #2159; Manufacturer Defendants' Opposition to Plaintiffs' Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them ("Mnf. Opp."), Dkt. #2181; Defendants' Response to Plaintiffs' Motion for Partial Summary Adjudication on Defendants' Compliance with the Controlled Substances Act [CSA Compliance Brief] ("Dist. Opp."), Dkt. #2180. The exhibits to Defendants' Mnf. Opp. and Dist. Opp. will be referred to herein as they were titled by Defendants for the Court (*e.g.*, "DSJ2A FCSAB Opp. Exh. #" or "DSJ2B FCSAB Opp. Exh. # Ex. #"). The paradox lies in Defendants' insistence that they complied with duties they contend they never had.

[3] As Plaintiffs explained in their opening papers, "suspicious orders" are those defined under the CSA to include orders of unusual size, pattern, or frequency. The determination that an order is suspicious does not mean that it is likely to be, or will be, diverted, but rather that further inquiry is needed to determine that

(footnote continues on next page)

question whether these duties exist as a general rule is, in any event, a question of law, ripe for adjudication on these summary judgment motions.[4]

Defendants' specific failures to comply with their CSA obligations, while matters of fact, similarly do not present disputed issues for trial. This is so because, in order to establish that Defendants violated their CSA duties, Plaintiffs need not establish that Defendants were never at any moment in compliance. Rather, Plaintiffs need only establish that during portions of the relevant time period, Defendants failed to establish and maintain compliant programs. Thus, Plaintiffs need not prove the Defendants never identified *any* suspicious orders in order to establish, as a matter of law, that Defendants' SOM programs were not designed to identify—and were incapable of identifying—the full range of orders defined as suspicious by the CSA, and thus did not comply with Defendants' obligations. Similarly, Plaintiffs need not show that Defendants never halted a single suspicious order, if their evidence shows that Defendants routinely shipped such orders without due diligence and maintained no policy requiring due diligence before shipment. For this reason, Defendants' evidence suggesting that at particular time periods, or on specific occasions, they may have occasionally complied, does nothing to undercut Plaintiffs' undisputed evidence as to Defendants' massive and ongoing violations. What Defendants do not and cannot show is a factual dispute with respect to Plaintiffs' evidence that the SOM programs of each of the Defendants were materially and systematically defective (and indeed, in some instances, entirely non-existent) during relevant time periods, even if, on particular occasions, Defendants happened to meet the

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diversion is unlikely. Thus, a determination, following due diligence, that an order is unlikely to be diverted does not retroactively mean that the order was not "suspicious," but rather clears the order for shipment, despite its being suspicious. A determination that an order is suspicious is analogous to a finding of "probable cause" for an arrest, while a finding that the order is nonetheless unlikely to be diverted is analogous to an acquittal at trial.

[4] In this regard, Plaintiffs note that, whether or not the CSA and the regulations impose a no-shipping duty as a matter of law, the failure to halt shipments pending a due diligence investigation would, in any event, be a factor to be considered in assessing a particular Defendants' compliance with the more general requirement to maintain effective controls against diversion.

requirements of the CSA.[5] Plaintiffs respectfully request that the Court grant partial summary judgment adjudicating that Defendants failed to comply with their CSA obligations.

ARGUMENT

I. THE CSA DUTY TO "MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION" REQUIRES DEFENDANTS TO IDENTIFY AND REPORT SUSPICIOUS ORDERS AND TO HALT SHIPMENTS OF SUCH ORDERS PENDING INVESTIGATION.

A. The CSA Imposes Affirmative Obligations on the Defendants.

Contrary to Defendants' assertion, the CSA does impose affirmative duties on registrants. The statute expressly authorizes the Attorney General to "promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C.A. § 821. The DEA, an arm of the Justice Department, has done precisely that. Thus, 21 C.F.R. § 1301.71(a) expressly commands that "[a]ll applicants and registrants *shall* provide effective controls and procedures to guard against theft and diversion of controlled substances." (emphasis added) As a result, the maintenance of effective controls against diversion is not merely a factor for the DEA to consider in granting or maintaining registrations, as Defendants would have it, but an affirmative duty of every registrant, including Defendants.

The DEA has also codified specific elements of what constitute effective controls against diversion. These include the so-called "security requirements," consisting of the duty to identify suspicious orders and to report those orders to the DEA when they are discovered. *See* 21 C.F.R.

[5] Defendants do identify a number of factual issues that are beyond the scope of this motion and that therefore do not defeat partial summary adjudication on the issues presented. For example, the "number of opioids that should have been shipped," *see* Dist. Opp., p. 2, may be a disputed issue of fact, and may be relevant to Plaintiffs' claims and/or Defendants' defenses at trial, but this question has nothing to do with whether the Defendants violated their duties under the CSA. Similarly, what particular DEA agents said to particular Defendants may raise disputed issues, but again does not affect the legal scope of Defendants' duties or the fact of whether they complied with them. There are many disputed issues of fact in these cases, and these issues can be resolved only at trial, but, as noted in the text, what Defendants cannot show is that there is any factual dispute about their failure to implement a system capable of identifying suspicious orders or their failure to block shipments pending a due diligence investigation.

§ 1301.74 (a registrant "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances" and "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant"). These duties are expressly set forth in mandatory language in the regulations and create duties that bind registrants who have been given the privilege of distributing controlled substances. The argument of the Distributors that because these duties are set forth in a regulation, rather than in a statute, they impose no affirmative obligations, *see* Dist. Opp., pp. 15-16, should be rejected as frivolous. *See First Tennessee Bank Nat. Ass'n v. Barreto*, 268 F.3d 319, 329 (6th Cir. 2001) ("It is well settled that a government agency's regulations that have been published in the Code of Federal Regulations have the force and effect of law.").[6]

Defendants' suggestion that, once suspicious orders have been identified, a registrant's only obligation is to report those orders to the DEA, should be rejected. The position is legally, logically, and morally indefensible. Rather, as explained below, the duty to provide effective controls against diversion, coupled with the duty to identify suspicious orders, necessarily entail that registrants suspend suspicious orders pending a "due diligence" investigation to determine whether the orders are likely to be diverted.

B. The Scope of Defendants' Obligations Is Determined by the Statute, the Regulations, and the Official Pronouncements of the DEA.

As set forth in Plaintiffs' opening brief, the CSA provides that, "[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally - to manufacture, distribute, or dispense a controlled substance . . . ." 21 U.S.C. § 841(a). The CSA requires the DEA to consider, as a primary factor in the grant of registration the maintenance of effective controls against diversion, § 823(a)(1), (b)(1), and further authorizes the DEA to consider the same factors set forth in § 823 in making a determination with respect to suspension or revocation of a registration, § 824. To effectuate these provisions, the statute authorizes the DEA to promulgate

[6] To the extent Distributors argue that the affirmative obligations imposed by the CSA regulations cannot constitute RICO predicate acts, that argument should also be rejected. *See infra* at § III.C.

regulations pursuant to which controlled substances may be lawfully manufactured and distributed. 21 U.S.C. § 821. The scope of the duties imposed on registrants is a question of law requiring construction of the statute, the regulations, and the DEA's rulings with respect to them.

As the Supreme Court has explained, "[t]he well-reasoned views of the agencies implementing a statute constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Indeed, the Court held, "we have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Id.*(citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)); *see also Cumberland River Coal Co. v. Banks*, 690 F.3d 477, 485 (6th Cir. 2012) ("A court should defer to an agency's interpretation of its own regulation . . . unless that interpretation is plainly erroneous or inconsistent with the regulation"). Although it is true that the DEA must determine, on a case-by-case basis, whether a grant or continuation of a registration is consistent with the public interest, and whether a particular registrant has complied with its statutory or regulatory obligations, it is also true that the DEA is empowered to determine, as a matter of law, that particular types of practices are inconsistent with the maintenance of effective controls against diversion and thus do not meet the requirements of the statute and the regulations. Moreover, as discussed below, the DEA is authorized to make such determination both through notice-and-comment rulemaking and through formal adjudication. *See* 21 U.S.C. §§ 821, 824; *see also Mead*, 533 U.S. at 230; *N.L.R.B. v. Bell Aerospace Co. Div. of Textron*, 416 U.S. 267, 293 (1974) (administrative agencies may promulgate standards through adjudications rather than through rule-making). In the case of the no-shipping duty, as discussed below, the DEA has found that shipment of suspicious orders without investigation is incompatible with the maintenance of effective controls against diversion. Defendants' argument that, in order to impose a "due diligence" or "no-shipping" requirement, the DEA was required to amend its regulations through notice-and-comment rule-making—and that registrants may ignore the formal adjudications of the DEA—was rejected by the Supreme Court more than 40 years ago. *Bell Aerospace*, 416 U.S. at 293.

C. The DEA Has Determined that the Maintenance of Effective Controls against Diversion Requires Registrants to Investigate and Halt Suspicious Orders.

The DEA has twice held, in formal adjudications, that the CSA and the regulations impose the no-shipping duty. *See Masters Pharmaceuticals, Inc.; Decision and Order*, 80 FR 55418-0, 2015 WL 5320504 (DEA September 15, 2015), *aff'd, Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007). Defendants ask this Court to disregard these decisions, arguing that they are neither legal precedent nor entitled to deference. Defendants are wrong.

To begin with, *Masters* is not merely an agency determination – it is also a decision of the United States Court of Appeals for the District of Columbia Circuit. The D.C. Circuit held:

> Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.

861 F.3d at 212-213. Although not fully binding, decisions of other federal courts of appeals on issues that have not been addressed by the Sixth Circuit are "entitled to deference and are persuasive precedents." *In re Perry*, 48 B.R. 591, 596 (Bankr. M.D. Tenn. 1985). Indeed, even the Sixth Circuit, which is not bound to follow decisions of other co-equal circuits, routinely "look[s] to our sister circuits for guidance when we encounter a legal question that we have not previously passed upon." *Bennett v. MIS Corp.*, 607 F.3d 1076, 1089 (6th Cir. 2010). Thus, "[a]s a general matter, we do not create conflicts among the circuits without strong cause . . . . because federal law (unlike state law) is supposed to be unitary." *Terry v. Tyson Farms, Inc.*, 604 F.3d 272, 278 (6th Cir. 2010), *quoting Washington Energy Co. v. United States*, 94 F.3d 1557, 1561 (Fed. Cir. 1996) and *citing Am. Vantage Cos., Inc. v. Table Mountain Rancheria*, 292 F.3d 1091, 1098 (9th Cir. 2002); *United States v. Auginash*, 266 F.3d 781, 784 (8th Cir.2001); *Mayer v. Spanel Int'l Ltd.*, 51 F.3d 670, 675 (7th Cir.1995). The *Masters* decision is persuasive precedent from the D.C. Circuit and is entitled to deference. That precedent, by itself, establishes the existence and contours of the no-shipping duty.

The underlying *Masters* DEA adjudication and the *Southwood* decision are agency adjudications, but they, too, are binding on Defendants and entitled to deference in this Court. In *Southwood*, the DEA held that the failure to perform proper due diligence and to halt suspicious orders constituted a failure to maintain effective controls against diversion warranting (among other factors), revocation of Southwood's registration. *See* 72 FR at 36498-99. The DEA held that "because registrants have a general duty to maintain effective controls against diversion, *they may not ignore indicators of diversion*. . . ." *Id.* at 36,500. In *Masters*, the DEA specifically affirmed the "due diligence" requirement, holding that

> a distributor's duty to perform due diligence on its customers stems from the requirement that a registrant "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a), as well as the registration requirements of section 823, which, in the case of a distributor, direct the Agency, in making the public interest determination, to consider the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical . . . channels."

80 FR at 55477. The DEA specifically rejected the argument that the "due diligence" requirement was inapplicable because it had been announced in an agency adjudication, rather than through rule-making, noting that "[t]he Supreme Court . . . long ago rejected the contention that an agency must announce all rules it adopts only through notice and comment rulemaking." *Id.* at 55476, *citing Bell Aerospace*, 416 U.S. at 290-95.

These decisions are entitled to deference in this Court. Although the Supreme Court considers a variety of factors in determining the degree of deference to accord an agency determination, a "good indicator" that such deference is warranted is "express congressional authorization[] to engage in the process of rulemaking or adjudication that produces regulations or rulings for which deference is claimed." *Mead*, 533 U.S. at 229;[7] *see also Varsity Brands, Inc. v. Star Athletica, LLC*, 799 F.3d 468, 478 (6th Cir. 2015) (deference to an agency interpretation warranted when "Congress provides for a relatively formal administrative procedure tending to foster the

[7] Indeed, *Mead* makes clear that formal adjudication stands on the same footing as notice-and-comment rulemaking with respect to the deference courts accord to agency findings. 533 U.S. at 230.

fairness and deliberation that should underlie a pronouncement of such force"), *aff'd*, 137 S. Ct. 1002 (2017).

The Controlled Substances Act provides exactly such express authorization and formalized procedure: § 824 specifically empowers the Justice Department to suspend or revoke registrations, precisely what occurred in *Southwood* and *Masters*. Plaintiffs note as well that *Southwood* and *Masters* are carefully-reasoned, formal adjudications reflecting both exceptional thoroughness and expertise on the part of the DEA. All of these factors point toward substantial deference to the agency's determination that controls against diversion cannot be effective if a registrant continues to ship orders it knows to be suspicious. *See Mead*, 533 U.S. at 228.

Defendants devote much ink to the specifics of the *Southwood* and *Masters* cases, and to their contention that their holdings are limited to their facts. But Plaintiffs do not argue that Defendants' registrations must be revoked under the reasoning of *Southwood* and *Masters*, only that these adjudications reflect a DEA determination that effective control requires that registrants suspend shipments of suspicious orders until it can be determined through due diligence that diversion is unlikely. In the end, however, Defendants concede that agency determinations like *Southwood* and *Masters* are "interpretive precedents." *See* Duties Opp., p. 18. Put another way, these decisions are equivalent to case-law construing or interpreting the CSA to impose a duty to suspend shipments pending investigation of suspicious orders. This Court should treat that finding as precedent and should similarly conclude that the CSA imposes this obligation.

D. The No-Shipping Duty Is Inherent in the Requirement to Maintain Effective Controls against Diversion.

Even if this Court gave no weight to *Masters or Southwood*, it can and should *still* find that Defendants were obliged to halt shipments of suspicious orders until it could be determined, through due diligence, that the orders were unlikely to be diverted. Even if it writes on a blank slate, this Court may, indeed, in this context, must, construe the CSA and its regulations to determine the scope of the duties imposed by the regulatory scheme. As discussed above and in Plaintiffs' opening brief, the no-shipping duty follows inexorably from the explicit regulatory commands to maintain

effective controls against diversion and to identify suspicious orders. How can controls against diversion possibly be effective if registrants are free to ship orders the DEA has defined, and registrants themselves have identified, as suspicious, without first investigating the likelihood of diversion? If the only purpose in identifying suspicious orders was to report them to the DEA, what would be the point of Defendants' affirmative obligation to maintain effective controls against diversion? Defendants' vision of the statutory and regulatory scheme—in which registrants simply identify and report suspicious orders, but all other steps to control diversion fall solely on the DEA—is flatly inconsistent with the DEA's explicit requirement that the *registrants* themselves must maintain effective controls over the supply chain. It is also inconsistent with a closed system that involves many thousands of participants and thus many thousands of potential diversion points. *See United States v. Moore*, 423 U.S. 122, 135 (1975) ("Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels . . . [and] was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."). Only by enlisting all of those many thousands of participants to keep watch can the DEA hope to control a supply chain involving so many parties. That is what the DEA regulations do – they require registrants to become part of the enforcement scheme, not merely to serve as passive information gatherers who can blithely ship controlled substances they know are likely to be diverted for as long as they can get away with it.[8]

The Distributors dispute that they play any role in policing shipments of controlled substances (Dist. Opp., p. 4), but their disagreement does not create a question of *fact*. Rather, examination of the CSA, its legislative history, the DEA's regulations (including the regulations requiring registrants to identify and report suspicious orders), as well as DEA case law demonstrates that, as a matter of *law*, Defendants are wrong about how the regulatory scheme is designed to

[8] Even if no prior decisions established this, Defendants can hardly complain that they had no notice of these duties, as both *Masters* and *Southwood,* along with the Rannizzisi letters, put them on notice. Whether or not DEA's repeated announcements were binding, Defendants disregarded them at their peril.

work. The importance placed in the statute on ensuring that registration of a particular applicant is "in the public interest," *see* 21 U.S.C. § 823(a), (b), is itself sufficient to establish that the CSA is predicated on the assumption that registrants must play a role in maintaining the closed system for narcotics distribution and in guarding against diversion. That the maintenance of effective controls is a primary consideration in the grant of registration, *id.,* and is a separate affirmative obligation of all registrants pursuant to DEA regulation, *see* 21 C.F.R. § 1301.71, is further confirmation that this is so. The role of registrants in ensuring that shipments are not diverted can be found throughout the regulatory scheme and has been specifically recognized by the DEA in formal adjudication. *See Southwood*, 72 FR at 36504 (the DEA cannot all by itself "protect the American people from [the] extraordinary threat to public health and safety" posed by prescription narcotics; it "must rely on registrants to fulfill their obligation under the Act to ensure that they do not supply controlled substances to entities which act as pushers."). Indeed, if under the regulatory scheme, registrants play no role in policing shipments of controlled substances, neither Master Pharmaceutical nor Southwood Pharmaceuticals would have lost its registration to failing to do so. Defendants' view that registration under the CSA is simply oligopoly protection for their profits and does not, in exchange for the privilege of selling controlled substances, require registrants to participate in enforcement responsibilities should be rejected, and does not, in any event, create an issue of fact.

The Manufacturer's argument that, whether or not there is a no-shipping duty, there is no duty to "know your customers' customer" should be rejected as semantic sophistry. As described above, Defendants' duty to maintain effective controls against diversion is clear. So is the duty to investigate suspicious orders and halt shipment until it can be determined through due diligence that diversion is unlikely. Once an order is flagged as suspicious, it is impossible for a registrant to determine that diversion is unlikely without investigation and consideration of the ultimate destination of the drugs. Whether or not there is a duty to "know your customers' customer" in the abstract, such a duty clearly exists in the context of the due diligence investigation necessary to clear an order as not likely to be diverted. *See Masters*, 80 FR at 55477 (requiring distributors to investigate legitimacy of prescriptions being filled by pharmacy when it has reason to suspect illegal dispensing

practices). This is especially true because, as explained in Plaintiffs' opening memorandum—and not seriously disputed by the Defendants—Defendants had available to them, through chargeback, 867, and IQVIA data, virtually complete visibility about the ultimate destinations of the drugs they shipped. Defendants' argument, that the CSA permitted them to ignore actual information in their possession, or readily available to them, about where their drugs were going, even for orders of unusual size, pattern, or frequency, as to which they were obliged to make a determination about the likelihood of actual diversion, cannot be seriously entertained. And while the question of whether any particular suspicious order was in fact likely to be diverted may be a disputed issue of fact, as discussed below, there is no dispute that most if not all of the Defendants never considered the information they had about downstream customers in determining whether to clear a suspicious order. This is not a question of second-guessing Defendants' individual judgments about particular orders and particular customers, but rather of the undisputed fact that Defendants made no effort to learn about the downstream destinations of the suspicious orders they received, and indeed decided *not* to learn about them, even as they collected and relied on that information for marketing purposes.

The Manufacturers' argument that the data available to them does not affect the contours of their obligations similarly misses the point. Defendants' obligations were to maintain effective controls against diversion, to identify suspicious orders, and not to ship those orders unless and until it had been determined that the orders were not likely to be diverted. The due diligence required to determine whether an order is likely to be diverted required Defendants to consult whatever information was available to them. Had downstream information been entirely unavailable, Defendants would have had to do the best they could with whatever information was available. But the downstream information *was* available, and Defendant's due diligence obligations did not permit them to ignore what they (or their sales departments) actually knew. Willful blindness to available information about diversion is simply incompatible with "due diligence" or with "effective controls against diversion." *See Masters* 80 FR at 55477 (registrant "cannot ignore information which raises serious doubt as to the legality of a potential or existing customer's business practices"). Thus,

Plaintiffs do not suggest that the information in Defendants' possession created new obligations, only that the systematic failure to use—or even to consult—the data in their possession establishes Defendants' failure to comply with the obligations they already had. Indeed, Congress recently recognized that this is true when it required the DEA to provide ARCOS data to CSA registrants. *See* 21 U.S.C. § 827(f)(3)(B) ("In determining whether to initiate proceedings under this subchapter against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or otherwise comply with the requirements of this subchapter or the regulations issued thereunder, the Attorney General may take into account that the [ARCOS] information made available under this subsection was available to the registrant.").

E. The SUPPORT Act Does Not Refute the Existence of the No-Shipping Duty.

Defendants argue that Congress's failure to include an affirmative statement of the no-shipping requirement in the 2018 SUPPORT Act demonstrates that no such requirement exists. They further characterize the provision of the act relied on by Plaintiffs in their opening brief, PL 115-271, § 3272, as a "background note related to a different provision in the 2018 amendments." But Chapter 7, in which this provision is found, is entitled the "Using Data to Prevent Opioid Diversion Act of 2018," PL 115-271, § 3271, a title that makes clear the relevance of the chapter to the issues presented on this motion. Section 3272, which sets forth the purpose of the chapter, is not a "background note"; it is a section of a public law duly enacted by Congress. The next section makes ARCOS data available to registrants to assist them in preventing opioid diversion. PL 115-271, § 3273. The reason for providing this information is clearly spelled out in the Public Law itself: it is "to help drug manufacturers and distributors identify, report, *and stop* suspicious orders of opioids and reduce diversion rates." *Id.* at § 3272(a) (emphasis added). Moreover, as set forth in Plaintiffs' opening brief, the statute includes a rule of construction:

> Nothing in this chapter should be construed to absolve a drug manufacturer, drug distributor, or other Drug Enforcement Administration registrant from the responsibility of the manufacturer, distributor, or other registrant to—
>
> (1) identify, *stop*, and report suspicious orders; or
>
> (2) maintain effective controls against diversion. . . ."

Id. at § 3272(b) (emphasis added).

Congress thus recognized that the responsibility to stop suspicious orders already existed, and went out of its way to provide that the receipt of ARCOS data did not *absolve* registrants of that obligation. Why would it have been necessary (or even sensible) for Congress to explicitly state that the new information would not absolve Defendants of an obligation they did not have in the first place? That new proposed legislation appears to assert that no such obligation exists is irrelevant—the proposed legislation has not been enacted and the understanding of its drafters (whoever they may be) about the scope of duties under the CSA cannot be presumed to be Congress's or the DEA's.[9]

F. Defendants' Evidence of Prior DEA Inspections and/or Purported Approval of Their SOM Programs Does Not Create a Triable Issue about the Scope of CSA's Requirements.

Defendants seek to turn a legal question—what duties does the CSA impose on registrants—into a factual one by referring to various DEA inspections and communications that purportedly show DEA's "approval" or "endorsement" of Defendants' SOM systems. In actuality most of this evidence shows nothing of the sort. *See, e.g., infra* at n.15. But even if this evidence accurately described the communications of certain DEA officials to a particular Defendant, it would not create a fact issue as to whether that Defendant violated the CSA. The DEA has repeatedly told "every entity in the United States registered with the [DEA] to manufacture or

[9] The Distributors suggest that, prior to the enactment of the SUPPORT Act, even the requirements to identify and report suspicious orders did not exist. Dist. Opp., p. 16 n.51. Their argument turns, first, on their untenable position that regulatory duties do not count, *see supra* § I.A-D, and § III, *infra*, and second on their disregard of the legislative history of the SUPPORT Act. Debates from within Congress confirm that the SUPPORT Act was intended to codify existing law and force registrants to do what the law says they are supposed to do. 164 Cong. Rec. S 6159-06, comments of Senator Cantwell at 34 ("One thing I really want to draw attention to is this issue of hearing over and over about how opioid manufacturers have flooded our communities when, in reality, current law says they are supposed to monitor and track the distribution of this drug. Well, in too many cases, those safeguards have not been followed"); *see also id.* ("What is clear, though, is that we need to do something now to make sure that opioid manufacturers follow the law that is already on the books about the reporting of suspicious distribution or volumes of distribution that are suspicious. Today, this legislation takes a major step forward on that front"). The Distributors' cases on this point, *Ross v. Blake*, 136 S.Ct. 1850 (2016) and *Pierce Cty., Wash. v. Guillen*, 537 U.S. 129, 135, (2003), involved *changes* in the law, rather than codification of existing regulatory requirements, and thus are inapplicable.

distribute controlled substances" that the "regulation clearly places the responsibility on the registrant to design and operate [a SOM] system[,]" and thus, "DEA does not approve or otherwise endorse any specific system for reporting suspicious orders."[10] Moreover, in December 2007, DEA informed all registrants that any "[p]ast communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system." Ps' Ex. 6 at p. 1.

But even prior to December 2007, to the extent any Defendant claims that it could not have violated the CSA because the DEA specifically approved its SOM system in direct communications with that Defendant, such purported approval fails to create a triable issue of fact. An administrative agency's purported pre-approval of conduct cannot exempt an entity from clear violations of a law.[11] As a matter of black-letter law, in the event an agency actually does express pre-approval of illegal conduct, Title 5, section 706 of the United States Code obligates a reviewing court to set aside and invalidate any such approval.[12] According to § 706, a reviewing court "shall"[13] determine the applicability of an agency action, and set aside that agency's actions, findings, or conclusions, if they are found to be "not in accord with the law." *Id.*

Courts may not disregard the plain text of a statute in favor of a contradictory administrative opinion. *See Athan v. United States Steel*, 364 F. Supp. 3d 748, 755 (E.D. Mich. 2019). Under the

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[10] Ps' Ex. 6 (2007 DEA letter) at p. 1; **Ps' Ex. 521** ABDCMDL00003659] (6/12/12 DEA letter) at p. 1 (same).

[11] Indeed, the idea that the DEA could pre-approve any defendants' conduct as lawful here is as preposterous as the idea that a police officer could pre-authorize someone's murder.

[12] 5 U.S.C. § 706 ("To the extent necessary to decision and when presented, the reviewing court *shall* decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court *shall* . . . (2) *hold unlawful and set aside agency action, findings, and conclusions found to be* - (A) *arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law*; (B) *contrary to constitutional right, power, privilege, or immunity*; (C) *in excess of statutory jurisdiction, authority, or limitations, or short of statutory right*; . . . . In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.") (emphasis added).

[13] "Section 706 is mandatory by its terms and not merely declarative of 'guidelines' with respect to the scope of judicial review of a federal agency's action." *Charlton v. United States*, 412 F.2d 390, 392 (3d Cir. 1969).

Chevron deference analysis, and as discussed in Plaintiffs' Duties MOL (pp. 8-9), "a court will not defer to an agency's construction if it is 'arbitrary, capricious, or manifestly contrary to the statute.' "[14] Moreover, the agency must have supplied a "satisfactory explanation" for its action. In *Tourus Records, Inc. v. Drug Enf't Admin*., 259 F.3d 731 (D.C. Cir. 2001), the court applied Section 706 to the DEA's decision on whether to grant approval of an application for *in forma pauperis*. In applying Section 706, the court found that, "[a]t a minimum, [Section 706(2)(A)] requires the agency to examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* at 763 (internal quotations omitted). The court went on to note that "[a] 'fundamental' requirement of administrative law is that an agency 'set forth its reasons' for decision; an agency's failure to do so constitutes arbitrary and capricious agency action." *Id.* at 737.

Plaintiffs note, as well, that Defendants go to great lengths to argue that the Rannizzisi letters do not constitute official rule-making or adjudications of the DEA and, as discussed above, attempt even to dismiss the DEA's formal adjudications as without precedential effect. But however mistaken this argument may be with respect to the *Masters* and *Southwood* decisions, which are formal DEA adjudications, the point is well taken with respect to any unauthorized, *ad hoc* pronouncements of DEA field agents regarding any of Defendants' SOM systems.

The scope of the duties imposed by the CSA is a legal question to be determined by the Court through construction of the statute and its implementing regulations, giving due deference to the official findings and adjudications of the DEA, the agency charged with implementing the regulatory scheme. Individual statements of DEA agents cannot and do not alter the contours of those duties.[15] Moreover, the *failure* of DEA agents to take action has even less value (if it possible

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[14] *Averett v. United States Dep't of Health & Human Servs*., 306 F. Supp. 3d 1005, 1012 (M.D. Tenn. 2018). *See also Thomas v. Abercrombie & Fitch Co*., 301 F. Supp. 3d 749, 758–59 (E.D. Mich. 2018); *Hughes Air Corp. v. C.A.B*., 482 F.2d 143, 145-46 (9th Cir. 1973) (setting aside agency action the court found to be "clearly wrong.").

[15] In many instances, moreover, the statements of the DEA on which Defendants rely are flatly contradicted by DEA enforcement actions as well as by Defendants' own admissions, in the context of settling those actions, that they had failed to comply with the CSA. *See, e.g.,* Ps' Ex. 31; **Ps' Ex. 522**

(footnote continues on next page)

to have less value than none) in assessing what it is the CSA and its regulations require of the Defendants.[16]

II. DEFENDANTS FAIL TO CREATE DISPUTED ISSUES OF FACT WITH RESPECT TO THEIR COMPLIANCE WITH THEIR CSA DUTIES.

Although Defendants submit evidence they contend creates a dispute concerning their compliance with the CSA, at best this evidence, if uncontroverted, would establish no more than Defendants were not necessarily in violation at every moment with respect to every order. In fact, Plaintiffs do controvert much of the evidence that Defendants submit and, if necessary, would do so at trial. However, in the context of these motions for summary judgment, Plaintiffs focus herein primarily on the facts Defendants *failed* to dispute which establish as a matter of law that Defendants violated the CSA. In particular, Plaintiffs focus here on undisputed evidence that Defendants failed to maintain SOM programs capable of identifying the full range of suspicious orders as that term is defined in the CSA and/or failed to comply with the no-shipping duty which required them to block shipments of suspicious orders unless and until it could be established through due diligence that the orders were unlikely to be diverted.[17]

A. Plaintiffs Have Identified Specific Suspicious Orders Shipped by the Manufacturer Defendants.

As a preliminary matter, before Plaintiffs address Defendants individually, it is important to

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]MCKMDL00337001] (McKesson). McKesson also claims that its settlement agreements with the DOJ, and DEA's letters in connection with same, do not constitute competent evidence on summary judgment. Even assuming, *arguendo*, that this settlement-related evidence is not admissible to establish the fact that McKesson violated the CSA (which Plaintiffs do not concede, *see, e.g., infra* at fn.122), it is admissible for other purposes, such as to show McKesson was on notice that the DEA/DOJ had taken the position that McKesson's SOM program did not comply with the CSA (*see, e.g.*, **Ps' Ex. 523** [MCKMDL00355350]). FED. R. EVID. 408(b) (noting the court "may admit this evidence for another purpose").

[16] Defendants cite *U.S. v. $463,497.72*, 853 F. Supp. 2d 675, 682 (E.D. Mich. 2012) in support of their contention that that the DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products and that practice had been approved by the DEA, *see* Dist. Opp., pp. 21-22. Even if the testimony cited in that case were competently offered in this case—which it is not—at most it would establish knowledge of registrants' practices on the part of particular DEA agent; it would not alter the legal contours of the registrants' duties.

[17] Plaintiffs reserve the right to prove, at trial, that Defendants' SOM programs, and any due diligence they did conduct, was inadequate as a matter of fact.

direct the Court's attention to a particularly misleading statement in the Manufacturer Defendants' Opposition. They assert that "Plaintiffs fail to identify a single order shipped by a Manufacturer to any customer—let alone shipment to a customer in either plaintiff county—that was suspicious and should have been withheld." Mnf. Opp., p.3. They rely on Plaintiffs' *initial* interrogatory responses, served July 5, 2018 (*id.* at p. 3 n.2), but ignore that Plaintiffs' experts have identified numerous orders shipped by Defendants (including Manufacturers) that should have been flagged as suspicious.[18] Plaintiffs' amended interrogatory answers note that this issue was the subject of expert testimony.[19] (Manufacturers ignore as well that Plaintiffs' amended interrogatory answers specifically identify suspicious orders shipped by Mallinckrodt.)[20]

B. Mallinckrodt Fails to Create a Disputed Issue of Fact.

Despite Mallinckrodt's protestations to the contrary, it has failed to create a genuine issue of material fact that (1) its SOM systems was capable of detecting suspicious orders as defined by the CSA; or (b) that it complied with the no-shipping duty. Rather, Mallinckrodt's "evidence" merely confirms Mallinckrodt's failure to comply with its obligations.

1. Mallinckrodt's SOM System Was Inadequate to Detect Suspicious Orders.

The undisputed evidence shows that Mallinckrodt failed to comply with its duty to identify suspicious orders because it relied primarily on a numeric threshold and failed to consider other factors, including the chargeback data it maintained, and the pattern and frequency of the orders, as required by the CSA and the regulations. Indeed, Mallinckrodt was specifically advised that its reliance on a numeric threshold was inadequate to identify suspicious orders, but continued to use this inadequate system nonetheless.

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[18] Keller Rep., Dkt. 2000-7; McCann Rep., Dkt. 2000-14; McCann Supp. Rep., Dkt. 2000-15; McCann Second Supp. Rep., 2000-15; Rafalski Rep., Dkt. 2000-22; Whitelaw Rep., Dkt. 2000-6.

[19] **Ps' Ex. 524** [excerpts from 3/4/19 Summit's Supp. Resps. to Manufacturer Ds' Interrogatories] at pp. 320-322, 327, 329; **Ps' Ex. 525** [excerpts from 3/4/19 Summit's Supp. Resps. to Distributor Ds' Interrogatories] at pp. 58, 60, 65, 68, 140-141, 147, 149; **Ps' Ex. 526** [excerpts from 3/4/19 Supp. Resps. to Pharmacy Ds' Interrogatories] at pp. 30-31, 37, 39.

[20] **Ps' Ex. 524** [excerpts from 3/4/19 Summit's Supp. Resps. to Manufacturer Ds' Interrogatories] at pp. 328-329.

The "disputes" that Mallinckrodt offers with respect to its reliance on a numerical threshold to identify suspicious orders are neither genuine nor material. First, there is no genuine dispute that Mallinckrodt relied on a numerical threshold formula to flag suspicious orders, and that Mallinckrodt had been informed its reliance on a numerical threshold was inadequate by both the DEA and its own independent consultant, Howard Davis.[21] Mallinckrodt does not dispute that Mr. Davis, who previously worked for the DEA and whom Mallinckrodt retained to evaluate its SOM program, criticized it for inappropriate reliance on a threshold formula.[22] Mallinckrodt also does not dispute that, even with respect to its own algorithm, it increased the threshold at certain times due to the "administrative burden" of reviewing the initial list of peculiar orders.[23]

In an effort to manufacture disputed facts, Mallinckrodt has identified "a comprehensive range of additional tools, procedures and systems to flag potentially suspicious orders." Mnf. Opp., p. 15. These "tools" are window dressing—purported features of a SOM policy that in reality were either not executed or inapplicable to identifying suspicious orders. For example, Mallinckrodt lists "a Dun and Bradstreet credit report check" as part of this "comprehensive range," but this credit report check was not related to suspicious order monitoring.[24] Mallinckrodt also lists "monitoring all incoming orders and escalating anything that looked potentially suspicious," Mnf. Opp, p. 16, but this is not an "additional" tool, as confirmed by Mallinckrodt's 30(b)(6) corporate designee, who testified that outside of the peculiar order numerical threshold, there was no separate system or

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[21] Rausch Tr., Dkt. #1970-3, at 194:3-23 (confirming that if an order was not flagged by Mallinckrodt's algorithm, it was not examined, and acknowledging that if there were gaps or faults in the algorithm, it was possible for problematic orders to get through); **Ps' Ex. 527** [MNK-T1_0000264260] (10/29/10 SOM Program No. C/S Comp. 3.0, establishing threshold for identifying "peculiar" orders and setting forth procedure for reviewing and classifying peculiar orders as "suspicious" and elevating these orders to DEA report status); **Ps' Ex. 528** [MNK-T1_0007146632] (12/27/07 Rannazzisi letter; "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders.").

[22] **Ps' Ex. 529** [MNK-T1_0000269399] (Som B, Memorandum from Howard Davis to Karen Harper, Suspicious Order Monitoring Program No. C/S Comp 3.0, (Nov. 2, 2010)).

[23] Harper Tr., Dkt. #1962-19, at 321:11-25 (justifying moving from a 2x to 3x formula because the peculiar order report was "too lengthy" and was creating too much of an "administrative burden").

[24] Rausch Tr., Dkt. #1970-3, at 155:13-156:24 (testifying that the Dun and Bradstreet credit report would not have helped prevent diversion and was "just a part of the credit department's ongoing procedure").

protocol for a customer service representative to identify a potentially suspicious order. Gillies 30(b)(6) Tr., Dkt. #1962-10, at 92:13-18. Mr. Gillies confirmed that customer service representatives "would not review every order prior to any identification of the order being peculiar." *Id.* at 93:3-94:2. Mallinckrodt's assertion that its SOM program always included "both an algorithm and non-algorithmic components," Mnf. Opp, p. 15, is therefore misleading. To the extent the SOM program included non-algorithmic components such as investigation by a customer service representative, that is only triggered *after* the numerical threshold flags picks up any peculiar orders. In other words, the non-algorithm features do not even apply if the initial algorithm is not triggered.

The "tools, procedures and systems" to which Mallinckrodt points do not alter the fact that Mallinckrodt relied primarily on a numerical threshold to identify suspicious orders—which was contrary to DEA guidance, ineffective, and, as Howard Davis warned, exposed Mallinckrodt to potential liability. At that time, Mallinckrodt was so displeased by Mr. Davis's criticisms that it fired him, under the pretext of allocating resources away from its SOM program.[25] Mallinckrodt's attempt to create genuine disputes of fact through post-hoc "improvements" to its SOMs system should be rejected.

2. Mallinckrodt Does Not Dispute that It Failed to Engage in Due Diligence and Halt Shipments.

Between 2003 and 2011, Mallinckrodt identified 37,817 orders as potentially suspicious, and out of these orders stopped, at most, thirty-three of them.[26] Mallinckrodt does not dispute its identification of the 37,817 orders, and while it claims to disagree with Plaintiffs' identification of 33 orders that were ultimately stopped, it has failed to come forward with any evidence contradicting this figure, nor does it offer any figure of its own. Indeed, the undisputed facts show, for example, that prior to 2008, Mallinckrodt only stopped "approximately 10 or less" orders. Harper Tr.,

[25] **Ps' Ex. 530** [MNK-T1_0000280821] (Nov. 17, 2010 email from K. Harper to herself characterizing Davis's termination as "Mallinckrodt 'firing' and Howard 'quitting'").

[26] Ps' Compliance MOL, pp. 30-31; Ps' Opp to Mallinckrodt MSJ, Exs. 66-78, Dkt. #2291-17-29.

Dkt. #1962-19, at 234:23 – 235:24. A party cannot create a dispute of fact by simply asserting—without any evidentiary support—that it disagrees with the other side.[27]

Thus, Mallinckrodt does not dispute that between 2003 and 2011 it identified 37,817 potentially suspicious orders, and Mallinckrodt does not meaningfully dispute that it stopped and reported a grand total of 33 orders. These statistics by themselves demonstrate a failure to comply with Mallinckrodt's "no shipping duty." It is inconceivable that during a period that covered the height of the opioid crisis, 37,784 potentially suspicious orders (99.9% of the orders flagged by Mallinckrodt) were determined after adequate due diligence to actually not be suspicious, particularly when Mallinckrodt, identified by the DEA as the "kingpin of the drug cartel," Ps' Ex. 34, had available to it chargeback data showing the large number of suspect pharmacies to which its products were shipped, and was well aware that its pills were being abused and diverted.

Even setting this quantitative evidence aside, Mallinckrodt does not dispute multiple facts demonstrating a failure to comply with its no-shipping duties. Mallinckrodt asserts, largely by ignoring large portions of the record, that the "SOM Team" had the "final say as to whether or not a product shipped." Mnf. Opp., p. 18. But Mallinckrodt does not dispute that: (1) the NAMs were the "eyes and ears and boots on the ground" for the compliance department; (2) these NAMs were conflicted because their bonuses were based on sales volume, and that Mallinckrodt recognized this conflict and did nothing about it; (3) a NAM was never penalized for failing to stop a suspicious

[27] Mallinckrodt's only factual dispute relates to the total number of orders that were shipped: under 1 million orders versus 53 million orders. Here again, the dispute is neither genuine nor material: Mallinckrodt identifies orders from distributors based on its sales data—that is, the number of orders placed by its distributor customers, while Plaintiffs are focusing on orders from indirect customers (to distributors) based on chargeback data. Mallinckrodt cannot dispute that there were, in fact, 53 million orders identified in the chargeback data—and that Mallinckrodt had the ability to track and evaluate these orders. But even if the Court were to consider only the one million direct orders by Mallinckrodt's distributor customers, the data still indicate that Mallinckrodt failed to maintain effective controls against diversion: Mallinckrodt stopped a total of 33 orders out of 37,817 suspicious orders, out of a total of approximately 1 million direct orders—less than 0.01% of total orders. Mallinckrodt is correct that there is no requirement under the CSA to report a set percentage of orders. But given the number of Mallinckrodt's direct and indirect customers who had their DEA licenses revoked, were criminally indicted, or prosecuted and sentenced to years in prison, it cannot be that only 0.01% of the orders Mallinckrodt filled were suspicious. These data reveal the stark reality: Mallinckrodt's SOM was deeply flawed and undeniably ineffective.

order; (4) and that notwithstanding their compliance obligations, NAMs were viewed as "advocates" for their customers. Ps' Ex. 34; Ps' Ex. 47.[28]

Mallinckrodt also does not challenge the accuracy of multiple emails identified in Plaintiffs' moving papers providing examples of potentially suspicious orders being cleared based on weak justifications provided by the NAMs: a customer was an "established customer;" a customer had a new downstream customers that wanted to order a lot of oxycodone; the NAM wanted to keep "momentum" rolling with a customer; a customer needed to increase its order volume to get favorable pricing; and a customer's inability to obtain opioids from another source justified filling an order many times above historical levels. Ps' Exs. 51-52, 54-55, 57. Nor does Mallinckrodt identify a single instance in which a NAM's justification for shipping an order was rejected. Moreover, as Harper herself admitted, she cannot recall a single instance in which a NAM recommended against shipping an order. Harper Tr., Dkt. #1962-19, at 341:24 – 343:1. Similarly, Ms. Neely, the product manager for oxycodone, was unable to recall a single instance in which she recommended against shipping an order, despite being potentially involved in hundreds, if not thousands, of orders of oxycodone. Neely Tr., Dkt. #1968-17, at 354:21 – 355:21.

In the face of this undisputed evidence, Mallinckrodt's response is to assert that "the ultimate decision" about whether an order was suspicious or not always rested with the "controlled substances compliance group." First, this group apparently only came into being in 2008.[29] Second,

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[28] Mallinckrodt's efforts to sideline its NAMs is understandable, given the undisputed evidence regarding whom Mallinckrodt hired for these important positions and how these employees viewed their jobs. With respect to Victor Borelli, one of their most productive and highly compensated NAMs, there is no dispute that he analogized opioids to Doritos chips, described his job selling opioids with the phrase "ship, ship, ship," emailed a customer telling him both to order more oxycodone whether inventory was low or not, and was described by a customer service manager as being willing to tell customer service representatives "anything they want to hear just so he can get a sale." Ps' Exs. 58-60. Borelli—who purportedly received SOM training—testified that whether opioid orders by a medical doctor from a distributor doing business as a veterinary supply company was suspicious was a "tough question to answer." Borelli Tr., Dkt. #1959-7 at 143:11 – 144:12. With respect to Steven Becker, another highly compensated NAM, there is no dispute that he had access to abundant information regarding problematic distributors, but never reviewed any of it. Ps' Ex. 67.

[29] **Ps' Ex. 531** [MNT-T1_0000496062] (Mallinckrodt SOM Team Charter (Apr. 7, 2011), showing team start date as 03/28/08); Gillies Tr., Dkt. #1962-10, at 101:7 – 102:2.

the only documentary evidence that Mallinckrodt can point to is a single 2013 email from Ms. New, relating to methadone, stating that the SOM Team and Jennifer B. [a member of the compliance department] have the final decision. DSJ2B FCSAB Opp. Exh. 21 Ex. 15. More fundamentally, Plaintiffs need not establish that the compliance department *never* stopped a suspicious order, or that *every* justification it accepted was flimsy. Plaintiffs' undisputed evidence clearly demonstrates repeated instances in which Mallinckrodt failed to comply with the no-shipping duty; this is sufficient to justify summary judgment against Mallinckrodt on this issue.

Moreover, Plaintiffs have offered unequivocal deposition testimony, confirmed by documentary evidence, that Mallinckrodt "did not always perform due diligence on peculiar orders before shipping them," a practice Ms. Harper admitted could result in failure to identify suspicious orders.[30] This practice clearly violates Mallinckrodt's no-shipping duties. In response, Mallinckrodt seeks to manufacture a dispute of fact by citing to a policy document stating that all unusual orders are subject to a ship hold pending investigation. Mnf. Opp., p. 17. This is inadequate to generate a genuine dispute of fact when one of Plaintiffs' primary arguments is that Mallinckrodt failed to adequately implement its stated policies. All Mallinckrodt has done is confirm that Rausch and Harper's "deal" to release orders without completing due diligence is yet another instance of Mallinckrodt's failure to adequately implement it anti-diversion program. In addition, evidence from other sources confirms Mallinckrodt's actual practice.[31]

Perhaps recognizing its inability to substantively dispute the damning evidence against it, Mallinckrodt resorts to semantics by arguing that it didn't "ship" anything into the Counties in the

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[30] Harper Tr., Dkt. #1962-19, at 199:24 – 200:10, 203:1-17. *See also* Ps' Ex. 42; Rausch Tr., Dkt. #1970-3, at 112:14-24 (stating that Rausch "did not always have the ability to do the thorough investigation" due to time constraints).

[31] *See* Ps' Opp. to Mallinckrodt MSJ, Ex. 79, Dkt. #2291-30 (email to J. Rausch from customer service representative B. Rehkop asking "[c]an we have the PS hold removed for our order flow?? This is the hold the system puts on 'suspicious' orders. We do not do anything with these orders except have to remember to release them."); *see also* Rowley-Kilper Tr., Dkt. # 1996-1, at 129:24 – 130:20, 134:19 – 135:3 ("They weren't holding the orders, so if it showed up on the [peculiar order] report, they were still shipping it out."); **Ps' Ex. 532** [MNK-T1_0000281241].

first place. This is a red herring. According to Mallinckrodt, Plaintiffs' statements regarding Defendants' "shipments" into Summit and Cuyahoga do not apply to Mallinckrodt, because "there is no evidence that Mallinckrodt shipped *any* opioid product to either Bellwether county at *any* time." Mnf. Opp., p. 14. But Mallinckrodt does not appear to dispute that it manufactured approximately 25% of the opioids (2.3 billion MMEs) supplied to the Bellwether jurisdictions between 2006 to 2014. McCann Second Supp. Rep., Dkt. #2000-16, at 4. As a manufacturer, Mallinckrodt shipped its products through wholesalers and distributors, and—as discussed above in the context of chargeback data—it had detailed information regarding sales to its indirect customers—as well as, in many instances, direct communications, including pricing negotiations, with these indirect customers. Mallinckrodt's attempt to distance itself from the massive volume of its opioids supplied to the Counties should be rejected. It manufactured the pills that were shipped to the Counties, it sold the pills to its distributor customers, and it carefully and methodically tracked the sale of these pills by its distributor customers to downstream customers in the Counties.[32]

Accordingly, Mallinckrodt has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to block shipment of, and investigate, suspicious orders.

C. Teva Fails to Create a Disputed Issue of Fact.

Teva, too, fails meaningfully to dispute Plaintiffs' evidence showing that its SOM system was not designed to and was not capable of detecting suspicious orders or that it shipped orders it did identify as suspicious without the requisite due diligence.

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[32] Under Mallinckrodt's flawed reasoning, by deliberately limiting shipments to a distribution center in a single state and relying on the distribution center to ship its products nationally, a manufacturer could effectively insulate itself from liability for any harm its products caused in the other 49 states. This cannot be the law. Mallinckrodt cannot avoid responsibility for the harm it has caused Plaintiffs because its core business consists of sales through distributors, which subsequently shipped Mallinckrodt's pills to downstream customers including in the Bellwether jurisdictions. Nor can Mallinckrodt avoid responsibility for the harm it caused Plaintiffs through ballooning sales of its opioids to indirect customers in other jurisdictions such as Florida—sales volumes that were only possible because many of those pills were carried right back out of Florida and into Ohio, as Mallinckrodt knew.

1. Teva's SOM Program Did Not Detect Suspicious Orders as Defined in the CSA.

Teva argues that it complied with the CSA simply because it had a SOM system in place, and by the mere fact it had a DEA compliance department. Mnf. Opp., pp. 28-29.[33] But just having a SOM system does not mean it is in compliance with the CSA or effective. Teva admits it was required to have an effective SOM system in place since the time it first started selling opioids, and that its obligations and the DEA's expectations to have an effective SOM system were accurately set forth in the DEA's letter to Teva in 2006.[34] And in 2012, Teva's own consultant—Ronald Buzzeo, who has been designated as an expert in the case by Mallinckrodt—found, among other things, that Teva's SOM system was "rudimentary," the SORDS SOM system it used at the time was unreliable in identifying suspicious orders, no written procedures were in place, *and not a single suspicious order had ever been identified by Teva* or reported to the DEA. Ps' Ex. 98 at *006. The fact that Teva had never identified a suspicious order is not surprising, as Buzzeo found that its SORDS SOM system was entirely deficient in detecting suspicious orders:

> Additional deficiencies were also noted during the review process. Three standard deviations in particular are insufficient to identify orders that may be suspicious. (Three standard deviations will only identify three out of 1,000 orders.) *The system further fails to identify frequency or pattern, two items specifically contained in the legal definition of a "suspicious order."* Also, the calculations are not performed on real-time data, since the history must be manually adjusted on a scheduled basis.

Ps' Ex. 98 at *009 (emphasis added).

The only evidence Teva provides to support its claim that its SORDS SOM system adequately identified suspicious orders is a declaration from its Senior Director of DEA

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[33] Teva claims Plaintiffs do not reference the SOM systems utilized by Cephalon and Actavis. Mnf. Opp., p. 28, n.29. But all three entities' systems are addressed by Plaintiffs' motion. After Teva acquired Cephalon in 2011 and the Actavis generic entities in 2016, they all utilized the same system. McGinn Tr., Dkt. #1966-20, at 393:21 – 395:6; Hassler Tr., Dkt. #1962-26, at 77:3-10, 85:13-24. Moreover, when Teva acquired Cephalon in 2011, Teva retained Cephalon employees and organizational structure for its own system. McGinn Tr., Dkt. #1966-20, at 14:1-17, 19:5 – 20:11; Hassler Tr., Dkt. #1962-26, at 77:3-10. Further, the deficiencies in the Actavis generic entities' SOM system before they were acquired by Teva in 2016 are set forth fully in Plaintiffs' motion. Ps' Compliance MOL, pp. 62-66.

[34] **Ps' Ex. 533** [TEVA_MDL_A_02063728]; McGinn Tr., Dkt. #1966-20, at 112:20-131:15; Tomkiewicz Tr., Dkt. #1971-9, at 174:17-200:13.

Compliance, Colleen McGinn. DSJ2B FCSAB Opp. Exh. 41 Ex. 35. She states: "That system, among other things, compiled average purchase quantities for each customer for each ordered product, set upper control limits based on the average sales data, and automatically pended orders that deviated from the customer's normal purchasing pattern while an investigate [sic] took place." *Id.* at ¶ 11.[35] First, she mentions nothing about the system's ability to identify orders of unusual frequency. *Id.* Moreover, her self-serving and conclusory declaration is not sufficient to create a fact issue as to whether Teva's SORDS SOM could identify orders of unusual pattern. *See Alexander v. CareSource*, 576 F.3d 551, 560 (6th Cir. 2009) ("Conclusory statements unadorned with supporting facts are insufficient to establish a factual dispute that will defeat summary judgment.").

In short, having a rudimentary SOM system does not equal compliance with DEA regulations, and falls far short of what the DEA informed Teva was required for an effective system. Accordingly, the undisputed evidence establishes that, at least prior to September 2012, Teva failed to comply with its CSA duty to identify suspicious orders.

2. Teva Shipped Suspicious Orders without Performing Due Diligence.

Teva claims Plaintiffs "cannot point to a single suspicious order" Teva "failed to identify, investigate, report, or halt." Mnf. Opp., p. 28. In fact, the inadequacy of Teva's SOM system is clearly illustrated by its failure in 2015 to stop shipment of a large and obviously suspicious generic oxycontin order by Publix for its Florida pharmacies. **Ps' Ex. 534** [TEVA_MDL_A01466124]. Teva's SOM manager, Joe Tomkiewicz, raised "red flags" with the order, including the product being "high-strength oxycodone ultimately going to Florida," and in quantities of high 40 mg dosages which he observed did "not appear to be normal for a retail pharmacy." *Id.* Upon further investigation of ten of the pharmacies, Tomkiewicz found prolific sales by nine of them of high-strength oxycodone (the tenth was near a cancer center), which was "a sought after product among abusers." **Ps' Ex. 535** [TEVA_MDL_A_0146220]. He further discovered extensive "pill mill

[35] It is not entirely clear whether she is referring to Teva's original SORDS system, the SORDS II system created in late 2012, or both. *Id.*

activity" for those pharmacies' top prescribers, including doctors who were previously disciplined, required large sums of cash up-front for service, sent "car-loads" of out-of-state patients to those pharmacies, and "trad[ed] prescriptions for sex with underage patients." *Id.*

Yet after Tomkiewicz raised these flags, he was "berated" and "bullied" by Teva's Senior VP of generic sales, Christine Baeder, for investigating Publix and for not releasing the order. In demanding release of the order, Baeder explained "Publix has 0.8% overall market share and we (Teva) are trying to capture generic market share." **Ps' Ex. 536** [TEVA_MDL_A_02063728]. Tomkiewicz continued to receive pressure from Teva's customer service representative, Marianne Geiger (who assisted with the Publix investigation pursuant to Teva's SOPs), to release the order even though Tomkiewicz told her "[w]e can't have any of the product going to Publix until we ok it--*the data was that bad*." **Ps' Ex. 537** [TEVA_MDL_A_01056182] (emphasis added). Despite these red flags, the Publix order was cleared even though it was indisputably suspicious and should have been reported to the DEA. Tomkiewicz Tr., Dkt. #1971-9, at 456:4-457:4.

Teva argues its current system uses "computer software, with proprietary algorithms, to review all orders" (Mnf. Opp., p. 30), but Teva does not mention its 2015 internal audit found that 95% of its orders are automatically released *without human review*, and of the remaining 5% put on hold, most were released within minutes and only a handful were ever investigated. Ps' Ex. 112. Tomkiewicz admitted these results were no better than before Teva put the DefOps system in place. Tomkiewicz Tr., Dkt. #1971-9, at 275:11-18. Teva further insinuates that because most of its customers are established customers with their own SOM systems in place, it does not have to monitor them as closely as other customers. Mnf. Opp., p. 31. But when Teva's Director of National Accounts, Jocelyn Baker, asked Tomkiewicz to release the Publix generic oxycodone order arguing Publix "was an established customer, is this really required?," Tomkiewicz resisted (to no avail), stating "please remember that Cardinal, McKesson, Walgreens and CVS are also established customers, all of whom had serious DEA penalties due to the mishandling of oxycodone in the state of Florida." **Ps' Ex. 534** [TEVA_MDL_A_01466124]. Teva also insinuates it does not have to monitor downstream customers (its customers' customers) (Mnf. Opp., p. 31), but both its Rule

30(b)(6) deponent and Tomkiewicz admit downstream customer monitoring is essential to an effective SOM system (agreeing with the 2006 DEA letter to this effect).[36] Teva also admits it had chargeback data at all relevant times that would have allowed it to monitor downstream customers for suspicious activity.[37]

Accordingly, Teva has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to block shipment of, and investigate, suspicious orders.

D. Endo-Affiliates Par Pharmaceuticals and Qualitest Fail to Create a Disputed Issue of Fact.

The undisputed evidence establishes that Endo-affiliates Par Pharmaceuticals and Qualitest violated the CSA because (1) during a portion of the relevant time period, it is undisputed that Par had no SOM system in place at all; (2) neither Par nor Qualitest had in place systems capable of detecting suspicious orders as defined in the CSA; and (3) both Par and Qualitest failed to halt suspicious orders pending due diligence.[38]

1. Par Had No SOM Policy in Place during a Portion of the Time It Sold Opioids.

Par's own evidence demonstrates that it had no SOM policy in place prior to at least April

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[36] Hassler Tr., Dkt. #1962-26, at 218:14-20, 219:2-6; Tomkiewicz Tr., Dkt. #1971-9, at 185:3-8; **Ps' Ex. 533** [TEVA_MDL_A_01039159] (2007 Rannazzisi letter).

[37] Tomkiewicz Tr., Dkt. #1971-9, at 380:3-380:7; Hassler Tr., Dkt. #1962-26, at 144:8-11. Teva further argues Cephalon sold only two opioid drugs approved for cancer use (Actiq and Fentora) and had only a few distributor customers, insinuating an excuse as to why it did not report any suspicious orders. Mnf. Opp., p. 31. But by 2006 it was selling close to $500 million per year of Actiq, and it was successful in transitioning many of those customers to Fentora in 2006 after Actiq lost its patent protection. **Ps' Ex. 538** [TEVA_MDL_A_00364495] (2007 Fentora Marketing Plan). And, as set forth here, Cephalon likewise had a duty to monitor not only their distributor customers, but also their downstream customers – and they knew that 90% of their opioid products were being used for off-label, non-cancer uses. **Ps' Ex. 539** [TEVA_MDL_A_01159323] (2005 Actiq Marketing Plan). In fact, Cephalon was fined $425 million in 2008 and pled guilty for its illegal off-label promotion of Actiq (for non-cancer use) and two other drugs. **Ps' Ex. 540** [Cephalon Sentencing Memorandum]; **Ps' Ex. 541** [9/29/2008 DOJ Press Release]; **Ps' Ex. 542** [Cephalon Guilty Plea Agreement].

[38] In their Motion, Plaintiffs acknowledged that Endo was not technically a registrant under the CSA, but explained that Endo had expressly and voluntarily assumed the duty to maintain effective controls against diversion. Ps' Compliance MOL, p. 44 n.62. Although Plaintiffs dispute the evidence Endo sets forth in its Opposition to refute this argument, there are admittedly questions of fact regarding this issue. Accordingly, Plaintiffs no longer seek summary judgment with respect to Endo, but reserve the right to argue at trial that Endo assumed duties under the CSA and violated those duties.

17, 2012. Mnf. Opp., p. 55 n.121.[39] Par claims that prior to 2011, it did not manufacture any Schedule II controlled substances.[40] However, the evidence clearly establishes that Par was selling opioids in 2010.[41] For example, in a May 2010 audit report (based on an audit conducted the previous month), Par's DEA consultants noted: "[W]hen Oxycodone HCI was being ordered, it was written only as Oxycodone, which would not be construed as Oxycodone Base." Ps' Ex. 169 at E1056.3-4. *See also id.* at E1056.6 ("Year-end reports for Narcotics (Morphine Sulfate, Oxycodone, Hydrocodone) have not been filed."). Additionally, Par's 30(b)(6) corporate representative, Stephen Macrides, admitted that Par was selling opioids in 2010.[42] Indeed, Par's own evidence demonstrates it was selling opioids that year.[43] Accordingly, the evidence is undisputed that Par was selling opioids without having a SOM policy in place, in violation of the CSA, from at least 2010 until at least mid-April 2012, and also from May 30, 2012 until October 4, 2012.

2. Neither Par nor Qualitest Maintained Systems Capable of Detecting Suspicious Orders.

Par does not and cannot dispute that, even when it implemented a SOM program in 2012, that program did not comply with the requirements of the CSA. *See* Plaintiffs' Compliance MOL, p. 53 n.123; Mnf. Opp., pp. 55-56. As Par's outside auditor stated in 2015: "There is no indication

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[39] Although there is evidence of a SOM SOP effective as of April 17, 2012, it states clearly at the bottom: "THIS DOCUMENT EXPIRES ON MIDNIGHT 5/29/2012." Ps' Ex. 170 at *274. Par's subsequent SOM SOP was not created until October 5, 2012. Par provides no evidence of a SOM SOP in place between May 30 and October 4 of 2012.

[40] In support, Par cites to a chart of total pills by year that it appears to have been created to respond to an interrogatory request. *Id.* at p. 55 n.120 (citing DSJ2D FCSAB Opp. Exh. 85 Ex. 79).

[41] There is also evidence Par was selling controlled substances prior to 2010. The 2005 Physician's Desk Reference notes Par was producing a number of CSA drugs in 2005, including Tramadol (an opioid painkiller), Caprisopordol (a muscle relaxant commonly combined with opioids), and Trizolam (a benzodiazepine). **Ps' Ex. 543** [2005 Physician's Desk Reference].

[42] Macrides Tr., Dkt. #1966-11, at 164:16 – 165:1 ("Q: Okay. Let's pause there. As of 2010, the company is selling controlled substances that it must keep in a vault and in a cage in its warehouse and production facilities, correct? A: Par was selling opioids that had certain regulations on how they needed to be stored and controlled.") (internal objection omitted), 174:17 – 175:1 ("Q: My question was, the company has been selling opioids for years prior to the time it implements its first SOP. Do you know that, sir? A: I have data here that says the company was selling opioids in 2010.").

[43] In its 10/12 SOM SOPs, Par attached a sample of a customer usage letter received by Par on October 1, 2010, in which the customer expressed its intent to purchase "Hydrocodone Polistirex" from Par starting in October 2010. DSJ2B FCSAB Opp. Exh. Ex. 80 at E1845.6.

that [Par's SOM] system measures or attempts to measure order size, pattern and frequency. These are the requirements in the regulations." Ps' Ex. 171 at *073. The evidence further demonstrates that this facially insufficient SOM system remained in force until October 2016.[44]

Similarly, Qualitest's program indisputably failed to comply with CSA requirements for the detection of suspicious orders until at least the spring of 2013. Although Qualitest attempts to dispute this, it fails to provide any evidence that its program had the properties Plaintiffs show it lacked. Instead, Qualitest relies almost exclusively on its purported cooperation with the DEA and the fact that the DEA did not take any action against them during that time period. *Id.* at pp. 52-53. As explained in § II.D.4 below, this DEA-related evidence is not sufficient to create a fact issue. The only evidence Qualitest provides regarding how its SOM system identified suspicious orders prior to 2013 is a concession that it told the DEA, in March 2013, "that its SOM program was 'currently based on historical purchases by individual customer (thresholds),' but that it was 'seeking to update the[ ] computer system and to improve the[ ] suspicious order monitoring system.' " Mnf. Opp., p. 53 (quoting Ps' Ex. 152). Qualitest has provided no evidence that its pre-2013 SOM system was designed or had the ability to identify orders of unusual size, frequency, or pattern as required by the CSA. Indeed, a September 2012 assessment of Qualitest's SOM program determined that "[m]onitoring and reporting [are] not meeting requirements." **Ps' Ex. 545** [PAR_OPIOID_MDL_0000035162] at p. 6. Accordingly, the undisputed evidence establishes that, prior to 2013, Qualitest failed to comply with its CSA duty to identify suspicious orders.

3. Par and Qualitest Failed to Halt Suspicious Orders Pending Due Diligence.

In their motion, Plaintiffs provided evidence that prior to 2013, when Qualitest would receive orders exceeding the customer's threshold, its employees would simply modify the orders by dividing them into several smaller orders to ensure each modified order cleared the threshold. Ps' Compliance MOL, p. 48. Plaintiffs also provided evidence that, in 2012, there were at least two occasions in which Qualitest shipped controlled substances it should not have shipped. *Id.*

[44] Macrides Tr., Dkt. #1966-11, at 248:16-22; **Ps' Ex. 544** [PAR_OPIOID_MDL_0002161313] at *13.

Additionally, Plaintiffs provided evidence that Qualitest would ship orders that fell within its own established threshold even when it knew that the customer had been limited in quantity for the same drug by another wholesaler. *Id.* at p. 49. In its Opposition, Qualitest does not even address, let alone provide evidence to refute, these contentions. Accordingly, the undisputed evidence establishes that, prior to 2013, Qualitest failed to comply with its CSA duty to block shipment of, and investigate, suspicious orders.

Similarly, Par does not dispute that orders that were flagged by Par's (wholly inadequate) system were cleared to ship. Ps' Ex. 134 at *414. Moreover, Par does not refute Plaintiffs' contention that its due diligence, to the extent it even occurred, was inadequate. Ps' Compliance MOL, p. 53. Accordingly, the undisputed evidence establishes that, between 2010 and 2016, Par failed to comply with its CSA duty to block shipment of, and investigate, suspicious orders.

4. DEA Inaction Does Not Create a Disputed Issue of Fact.

Although Par and Qualitest contend that the DEA approved their SOM programs as compliant, they submit no evidence to show that this is true. Indeed, Qualitest fails to provide any evidence that the DEA actually passed on its activities, or, further, evidence that Qualitest complied with its stated procedures. Rather, the record demonstrates the reverse. Compliance MOL, pp. 47-54.

Defendants' contention that the DEA allegedly found Qualitests' SOM-related practices to be compliant during the 2008 meeting is founded on the self-serving impressions of one of Defendant's employees after a request from DEA for its SOPs. Defendants offer no evidence that DEA actually approved Qualitest's SOPs, let alone evidence that Qualitest actually did what its procedures said it would. Rather, the record demonstrates the opposite. When consultants (and, later, internal DEA compliance personnel)[45] examined the Company's actions, they were found to be non-compliant with the CSA and associated regulations.[46]

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[45] Just two months after meeting with DEA in November of 2011, Qualitest personnel reached out to a different SOMS consultant seeking a meeting, writing "[…] *we are well aware that what we have is NOT compliant* by today's standards." **Ps' Ex. 546** [PAR_OPIOID_MDL_0001656118] at *120 (emphasis added). (footnote continues on next page)

Qualitest also points to a March 2013 report of a DEA meeting, but its quotation is incomplete. As examination of the document shows, DEA's actual evaluation of Qualitest's SOMS program is clear, and bears repeating: "SC Levin [of DEA] stated Qualitests' [sic] current system as explained to him and as seen in their ARCOS data is *inadequate* to say the least." Ps' Ex. 151 at *201 (emphasis added). Indeed, it was only when threatened by the DEA in 2013, with a tight timeline to cure the failings of its SOM programs, that Qualitest provisioned funding and sought to implement procedures to comply with its obligations.[47]

Similarly, Par's reliance on DEA inaction is unavailing. Par provides no records of the DEA's actual impressions or conclusions from its inspections, instead relying on second-hand accounts in reports by Par's consultants. Mnf. Opp., p. 56 n.124-125. There is no indication the DEA even reviewed Par's SOM program during that inspection, much less that it approved it.

E. Purdue Fails to Create a Disputed Issue of Fact.

The undisputed evidence shows that Purdue shipped suspicious orders without engaging in the requisite due diligence. Purdue contends that it had controls in place to hold orders that

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Furthermore, Tracey Norton, head of Qualitest's DEA compliance from 2011 to 2014, acknowledged that when she arrived at Qualitest in 2011, "[t]he [SOMs] program reported into sales and it was basically managed by two individuals; no customer visits occurred other than sales visits. Without going into detail, the program was *minimal* at best." **Ps' Ex. 547** [HDS_MDL_00404792] at *794 (emphasis added). As Ms. Norton candidly acknowledged, as of 2011, "[she] was very concerned with the status of the program…." *Id.* Similarly, in January 2013, Norton, Qualitest's head of DEA compliance, rated the SOMs program to be in "potential failure mode", with a "Total Risk Rating" of 25. **Ps' Ex. 548** [PAR_OPIOID_MDL_0000363469] at p. 24. This rating was higher (*i.e.,* worse) than any for any other risk Norton identified at the time. Norton Vol. I Tr., Dkt. #1968-21, at 390:17-24. Moreover, Norton indicated that, although the Qualitest "DEA compliance [group had] developed a plan for a new system," "[…] resources are limited." Specifically, funding was needed for IT resources and for customer assessments. **Ps' Ex. 548** [PAR_OPIOID_MDL_0000363469] at p. 24.

[46] For example, in August 2008 and July 2009, Qualitest's external DEA consultant audited Qualitest's actual procedures as implemented against what was written in its policies. In both 2008 and 2009, the consultant found deviations from the protocol. In 2009, he found that Qualitest was reducing order quantities to fall below limits coded into its own system so that they could be released. Ps' Ex. 148 at *177. In 2008, he found that Qualitest was shipping drugs to pharmacies that sales staff were aware had had their quotas limited for the same products. Ps' Ex. 147 at *110.

[47] Macrides Tr., Dkt. #1966-11, at 426:18-22 (Q. "Please tell the jury when the company first implemented a statistically validated algorithm." A. "In 2013 we engaged with Cegedim to do that."); Norton Vol. I Tr., Dkt. #1968-21, at 155:5-7 (Q. "And you are going to start doing due diligence visits [after meeting with DEA], right?" A. "Yes.").

exceeded the average by 20 percent, and that a Purdue executive reviewed those orders before they could be shipped,[48] but the undisputed evidence shows that on multiple occasions, Purdue cleared these orders without conducting any meaningful due diligence.[49] Moreover, although Purdue and the other Manufacturer Defendants erroneously dispute that they had any obligation to "know their customers' customers" (*supra* at pp. 10-12), the evidence submitted by Purdue shows that in fact Purdue routinely gathered such information. Its report to the DEA about the "slow" pharmacies demonstrates that Purdue in fact monitored the volume of sales at pharmacies. Similarly, Purdue touts its OMS committee that worked to identify potentially problematic pharmacies based on data-based algorithms. As noted above, however, Purdue did not use this information to determine whether suspicious orders were likely to be diverted, to halt shipments that would be sent on to problematic pharmacies, or to report problematic pharmacies to the DEA. The evidence shows that whether or not it had an obligation, Purdue in fact did know its customers' customers—and disregarded that information when it came to providing effective controls against diversion.[50] It thus failed to perform due diligence before shipping orders it knew to be suspicious.

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[48] Purdue also makes much of Plaintiffs' reliance on only one of Purdue's SOMs policies, noting that the policy was revised and updated at various times. But even if it was true that Purdue's later policies were compliant with the CSA—and Purdue fails to provide any evidence that this was so—that does not alter the inadequacies of the particular policy identified by the Plaintiffs. The Court need not find that Purdue *never* complied with its CSA duties in order to find that it had no compliant policy during at least a portion of the relevant time period.

[49] For example, the particular order Purdue points to (which was 22.73% over the six-week average for Smith Drug) was held for just over three hours. Seid Vol. II Tr., Dkt. #1970-20, at 315: 23 – 318:18. Another order (that exceeded H.D. Smith's six-week average by 63.64%) was approved in under an hour. A third order (from Smith Drug that was 146.26% above average) took "about 30 minutes" to approve. *Id.* at 321:7 – 323:20. Most egregiously, Purdue cleared (1) an order from H.D. Smith that was 133.41% above average in *under ten minutes*, (*id.* at 324:23 – 325:8); and (2) an order from Cardinal Health that was 95% above average *in two minutes*, (*id.* at 325:24 – 326:7). With respect to this last order, the Purdue executive in charge of clearing suspicious orders admitted that in the two minutes the order was held he could not have done any investigation "other than what [he] knew of the account." *Id.* at 326:8-12.

[50] Defendants' citations to the testimony of James Rafalski are also inaccurate. They cite Rafalski in support of their argument that chargeback and similar data did not provide Manufacturers with sufficient data to monitor the supply chain. But although Rafalski acknowledged that time-lags resulted in gaps in the chargeback data, he also testified that this data can nonetheless provide "averages and levels and conduct that could be used in a suspicious order monitoring system." Rafalski Vol. II Tr., Dkt. #1969-19, at 719:14-16. Defendants also quote Rafalski saying Purdue in fact conducted due diligence. But although Rafalski testified that Purdue did "some" due diligence, he also testified that it "failed to use consistent algorithms and failed to

(footnote continues on next page)

F. Janssen Fails to Create a Disputed Issue of Fact.

1. Janssen Failed to Identify Suspicious Orders.

Janssen fails to create a disputed issue of fact with respect to its compliance with its duty to identify suspicious order, for two reasons. First, Janssen did not initiate a SOM program until mid-September 2005, despite having sold opioid products since the 1990s. Ps' Compliance MOL, p. 54; Ps' Ex. 180 at *176; Ps' Ex. 181 at *200. Janssen fails to address, let alone dispute, this point. Accordingly, the evidence is undisputed that Janssen was selling opioids without having a SOM policy in place, in violation of the CSA, until mid-September 2005.

Second, Janssen's SOM program was inadequate to identify suspicious orders. Janssen claims that its "algorithm appropriately identified 'orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.' " Mnf. Opp., p. 37 (quoting 21 C.F.R. § 1301.74(b)). But Janssen completely ignores and fails to refute the testimony of its head of suspicious order monitoring, Michele Dempsey, that (i) Janssen's algorithm *did not* consider frequency or pattern, and (ii) *only* an order flagged for unusual *size* by the algorithm could be stopped for review in real time.[51] Moreover, in 2018, an independent SOM auditor hired by Janssen issued a report stating:

> Stop using the current single criterion algorithm which selects and holds orders from customers when the quantity of an order is greater than three times (300 percent) the customer's average weekly order, based on a rolling twelve (12) month ordering history from that customer. *This algorithm only measures quantity and does not consider frequency or pattern of ordering by the same customer*. The algorithm compares a customer's order quantity against only that customer's average annual purchases. The algorithm would not detect multiple customer orders during a given week; it would not detect orders which consist of gradual quantity increases of a controlled substance over time; it would not detect a new customer's orders for controlled substances which initially commence with larger than normal quantities and remain at a constant level.

Ps' Ex. 549 [JAN-MS-05444650] at p. 10.

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investigate suspicious orders identified by the algorithms," and failed to investigate "on a consistent basis." *Id.* at 779:12-15, 780:4-12.

[51] Dempsey Tr. Vol. II, Dkt. #1961-13 at 453:8 – 455:13, 472:19 – 473:18, 512:20 – 513:5, 803:19 – 804:9, 811:24 – 813:7. *See also* Ps' Compliance MOL, pp. 55-56.

Janssen attempts to confuse the issue by arguing that some orders flagged for unusual size by its algorithm could also illustrate a deviation in pattern or frequency, and that it manually investigated any order its algorithm had flagged. Mnf. Opp., p. 38. Janssen misses the point. Its SOM system only flagged (and therefore only investigated in real-time) orders of *unusual size* as compared to the customer's past orders of the same exact SKU. Ps' Compliance MOL, pp. 54-57. The system was *not* designed to monitor and flag orders of unusual size or frequency, as required under the CSA. In other words, an order that did not exceed the algorithm's quantity threshold, but otherwise deviated from the customer's normal pattern or frequency, would not be flagged by Janssen's SOM system and would thus not be investigated prior to shipment. Accordingly, the undisputed evidence establishes that Janssen failed to comply with its CSA duty to identify suspicious orders.

2. DEA Inspections Do Not Create an Issue of Fact.

Janssen claims that its "perfect compliance record following numerous multi-day DEA inspections since 2006 alone would permit a reasonable jury to conclude that Janssen's suspicious order monitoring system complied with the CSA." Mnf. Opp., p. 35. In actuality, Janssen has failed to produce evidence that the DEA came on-site to Janssen's facilities with a *primary* inspection purpose to review Janssen's SOMs. Rather, the opposite is true. For example, Janssen cites an internal e-mail summarizing "Day 1" of an 8/08 DEA inspection of Janssen's Franklin Distribution Center in New Jersey.[52] That e-mail did not evidence a SOMs evaluation by the DEA.[53] Although the same e-mail indicates that, on Day 2, "Investigators are expected to complete the inventory reconciliation, review handling of suspicious orders, and conduct a security review,"[54] oddly, Janssen has been unable to locate any Day 2 summary, and Ms. Dempsey testified that she was not present

[52] DSJ2B FCSAB Opp. Exh. 50 Ex. 44.

[53] Dempsey Tr. Vol. II, Dkt. #1961-13 at 773:12 – 774:1.

[54] DSJ2B FCSAB Opp. Exh. 50 Ex. 44, at p. 2.

for Day 1 or Day 2 of the inspection, nor does Ms. Dempsey have any first-hand knowledge about the inspection.[55]

Similarly, Janssen cites an internal e-mail dated 7/30/13 titled, "Notice of inspection at KDC, 29 July 2013," summarizing a DEA inspection of Janssen's Kentucky Distribution Center.[56] Significantly, the primary areas reviewed during this DEA inspection were "Security (alarm) testing," "security and records," and the like. *Id.* at *994. Janssen's notes indicate that Janssen gave the DEA "SOPs and overview" concerning Janssen's SOMs. *Id.* at *001. But the mere provision of paper copies of Janssen's SOM overview and standard operating procedures would enable the DEA to do nothing more than a review of "SOMS Compliance Protocol on paper." *Masters*, 861 F.3d at 225. Yet that is precisely what the D.C. Circuit Court held could not be relied upon by a defendant for evidence that its SOMs is adequate, even when DEA didn't subsequently criticize the SOMs. *Id.* at 224-25.

The other six summaries of DEA inspections of Janssen facilities cited in the Opposition also do not create a fact issue defeating summary judgment.[57] None of the "Primary Areas Reviewed" in any of these DEA inspection summaries includes SOMs, and, where SOMs is mentioned in any way, the description is the same type of cursory "paper" review the *Masters* court deemed insufficient evidence for proving a defendant's SOMs is adequate and/or in compliance with the CSA. The *Masters* case and the above examples of Janssen's DEA inspection summaries, show that Janssen's boast of a "perfect" compliance record is not evidence of an adequate SOMS that complied with the CSA.

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55 Dempsey Tr. Vol. II, Dkt. #1961-13 at 774:2 – 775:10.

56 DSJ2B FCSAB Opp. Exh. 46 Ex. 40.

57 DSJ2B FCSAB Opp. Exh. 47 Ex. 41; DSJ2B FCSAB Opp. Exh. 48 Ex. 42; DSJ2B FCSAB Opp. Exh. 51 Ex. 45; DSJ2B FCSAB Opp. Exh. 49 Ex. 43; DSJ2B FCSAB Opp. Exh. 52 Ex. 46; DSJ2B FCSAB Opp. Exh. 53 Ex. 47.

G. Allergan Fails to Create a Disputed Issue of Fact.

Allergan failed to comply with the CSA both in failing to maintain a SOM program capable of detecting suspicious orders and in failing to hold suspicious orders pending due diligence.

1. Allergan's SOM System Did Not Comply with the CSA with Respect to the Identification of Suspicious Orders.

The evidence is clear, and Allergan does not deny, that the automated portions of Allergan's[58] and Actavis' SOM systems only concerned themselves with orders of unusual size.[59] In 2007, Actavis and Watson were told by the DEA that this was insufficient.[60] Indeed, they were told that while the regulation required analyzing orders on those three bases, even doing just that was not enough. The evidence is also clear that corporate policy prevented the companies from upgrading their inadequate systems. For example, Actavis CEO Douglas Boothe testified he believed the company had no "responsibility for, accountability for preventing diversion." Ps' Compliance MOL, p. 66 (citing Ps' Ex. 498 (Boothe Tr., Dkt. #1959-6, at 408-409)). Defendants try to rehabilitate this damning admission, but Boothe was clear: he said the sole purpose of the SOM system was "for making certain that the orders that we received were valid from licensed pharmacies and were within our suspicious order monitoring thresholds … that was our responsibility." *Id.* His statement contradicts the DEA guidance, the CFR rules, and the CSA itself.

Defendants also seek to downplay the statements of Nancy Baran, Senior Manager of Actavis's Customer Service Department. Mnf. Opp., p. 43. Baran criticized the system's "frequency" check as "not cumulative" (*i.e.*, "if a customer's monthly usage is 3000 units - they can order 2999 units every day of the month and it would not be caught") and for numerous other reasons. Ps' Compliance MOL, p. 63 (citing Ps' Ex. 487). As she summed up, "[t]he intent of the DEA suspicious report was designed to prevent excessive shipments of controlled products. In my

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[58] Allergan's SOM system descended from that of Watson Pharmaceuticals, Inc., with which it merged in 2015. Ps' Compliance MOL, p. 62.

[59] Ps' Compliance MOL, p. 63 (pre-merger Actavis), 67-68 (Watson and post-merger Actavis).

[60] **Ps' Ex. 550** [Allergan_MDL_03799223] (12/27/07 Rannazzisi letter to Watson).

opinion, it does a lousy job at even that." Ps' Ex. 487. Defendants now argue Baran was discussing something other than the SOM system, but, like Actavis CEO Boothe, Baran was clear. As she stated in the same document: "When time permits, I would be happy to sit with anyone interested and help you see why this is not the mechanism to prevent shipping excess product that one may believe." *Id.*[61]

As to the Watson SOM system, which survived the Watson/Actavis merger, Defendants again ignore that the automated portion of the Watson SOM system never addressed "orders deviating substantially from a normal pattern, and orders of unusual frequency," thereby violating 21 C.F.R. §1301.74(b). Allergan implies that the Watson system examined the frequency and pattern of orders via a "class of trade" analysis (Mnf. Opp., p. 47) but, as with Actavis's system, Watson failed to examine cumulative amounts of orders over a month, so, as Baran noted with Actavis's system, "if a customer's monthly usage is 3000 units - they can order 2999 units every day of the month and it would not be caught." Ps' Ex. 487.[62]

Accordingly, Allergan and Actavis have failed to raise a triable issue of fact refuting Plaintiffs' assertion that they failed to comply with their CSA duties to identify suspicious orders.[63]

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[61] Actavis had only one DEA reporting system from 2000 through October 2012, and it is the system that Baran denounced. Ps' Ex. 484. As Baran told co-employees at Actavis in 2009 when reviewing the SOM system for the legal department, "[o]ne thing I can say for sure - I am not going to stick my neck out there and speak to how tight of a process we have because we really don't." **Ps' Ex. 551** [Allergan_MDL_04333192]. When Watson employees examined the Actavis system in August 2012 as part of the corporate takeover, Mary Woods, who oversaw Watson's system, stated plainly that Actavis' SOM system was insufficient: "Definite risk right now today, current system is not acceptable to Watson." Woods Vol. II Tr., Dkt. #1972-11, at 172:6-20; **Ps' Ex. 552** [ALLERGAN_MDL_03776365]. Woods continued that "[t]here is no current SOP on the current process" and that it used a "threshold base" as the logic. Woods Vol. II Tr., Dkt. #1972-11, at 173:16-177:15; **Ps' Ex. 552** [ALLERGAN_MDL_03776365].

[62] Allergan also tries to minimize the admissions of Watson's and post-merger Actavis' employees, who affirmatively state that the SOM system did not comply with the law. Ps' Compliance MOL, p. 68. In the end, however, they cannot avoid that Thomas Napoli, the head of DEA Affairs at Watson, told his superiors in 2011 that the SOM system was "not consistent with specific requirements noted within regulations and guidance," or that he asked for money to establish a system to "[f]ully address specific regulatory requirements." *Id.* The system he criticized was never replaced. Instead, Napoli was laid off. *Id.*

[63] Allergan, which still profits from the sales of two opioids, Norco and Kadian, argues that it can no longer held liable for diversion of its drugs because it outsources all of its manufacturing and delivery and no longer holds a DEA registration. Mnf. Opp., p. 48. Yet, as the owner of the drugs, Allergan still manages the sales of the drugs at issue, and has access to detailed downstream information about them. Considering this (footnote continues on next page)

2. Allergan Violated the No-Shipping Duty.

Defendants' evidence does not create a fact issue as to Allergan's and Actavis's failure to investigate and block suspicious orders. When Watson employees examined the Actavis system in August 2012 as part of the corporate takeover, Mary Woods, who oversaw Watson's system, stated plainly that Actavis' SOM system was insufficient: "Definite risk right now today, current system is not acceptable to Watson."[64] Woods stated that the system "does not hold orders" automatically, and instead just "creates a report" for workers to investigate.[65] Woods continued that under the Actavis processes, employees "do not investigate all, only some, since there is no SOP, they don't investigate."[66]

Defendants' assertion that pre-merger Actavis used "Chargeback data" (Mnf. Opp., p. 42) is completely unsupported. They cite to passing testimony from Jinping McCormick, who was the head of generic marketing at Actavis—not the DEA Affairs group. Regardless, when asked whether she remembered using chargeback data as part of the SOMS processes, McCormick stated "I don't recall anything that really stands out as of today." McCormick Tr., Dkt. #1966-19, at 189:19 – 190:1. Actavis's policy did not incorporate the use of such data, and there is no evidence that pre-merger Actavis used it in the SOMS process. To be sure, pre-merger Actavis installed a working SOMs system designed by the Buzzeo group in October 2012 that could potentially use the downstream data, but Watson turned it off in January 2013 when it bought Actavis.[67]

Similarly, Allergan concedes that the "automated portion of the [Watson SOM] system did not utilize any downstream customer information available." Mnf. Opp., p. 45. Yet it exonerates

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access to data, if Allergan is on notice of continuing diversion that started when it was a registrant, it must be held to account for not stopping it. Regardless, Plaintiffs are only seeking summary judgment regarding Defendants' violations of the CSA during the period 2000-2016. Ps' Compliance MOL, p. 143.

64 Woods Vol. II Tr., Dkt. #1972-11, at 172:6-20; **Ps' Ex. 552** [ALLERGAN_MDL_03776365].

65 Woods Vol. II Tr., Dkt. #1972-11, at 173:16-177:15; **Ps' Ex. 552** [ALLERGAN_MDL_03776365].

66 Woods Vol. II Tr., Dkt. #1972-11, at 177:18-178-3; **Ps' Ex. 552** [ALLERGAN_MDL_03776365].

67 *See* Plaintiffs' Memorandum in Opposition to Allergan Defendants' Motion for Summary Judgment ("PSJ10"), Dkt. #2186, at p. 11.

itself because, it says, such information was used when orders were "manually investigated." *Id.* at p. 46. But manual investigation only occurred if the automated portion flagged an order.[68] Orders that passed through the automated portion of the system were shipped without any further analysis. *Id.* It does not matter whether the system used downstream information in manual analysis, as the questionable orders would already be out the door.

Allergan also states that tripling the number of investigations handled per month by its staff did not cause them to perform "any less effectively." Mnf. Opp., p. 47. In reality, however, Watson's SOMS staff was so inundated with orders it was "impossible for [them] to enter the information in the SOMS share drive folder for all customers." **Ps' Ex. 553** [Allergan_MDL_04176625]. Instead, the staff was allowed to make arbitrary decisions regarding whether to ship a pending order, "if it was over by a few bottles" with no further documentation. *Id.* Similarly, Allergan argues that it should be excused for Watson having a policy that affirmatively allowed the cutting and cancelation of orders, because it required customers to "provide a reason." **Ps' Ex. 554** [Allergan_MDL_01175574]. Yet Nancy Baran, who worked at the combined Watson/Actavis company, made it clear: "'Cutting' orders to a volume that puts the order under a threshold is not acceptable," and that the "DEA has stated on this topic, 'That is like saying a little bit of diversion is okay.' " **Ps' Ex. 555** [Allergan_MDL_03368470].[69]

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[68] Ps' Ex. 506 (noting that only orders that generate a "SOMs excessive order flag" in the automated "SAP" system are subject to further review).

[69] Allergan also seeks to "spin" the disastrous September 2012 meeting where DEA employees treated Actavis employees, including its Ethics and Compliance Officer Michael R. Clarke, "as street dealers." Clarke Tr., Dkt. #1959-25, at 86-89. At that meeting, the DEA made clear that Actavis's drugs were being diverted from Florida and other locations showing, for example, that in one month in 2011 Florida received more than six times the amount of Actavis Oxycodone than the next highest state. Ps' Compliance MOL, p. 64 (citing Ps' Ex. 496). According to the DEA's contemporaneous notes, agents asked Baran to send Actavis employees to Florida so they could, among other things, "witness the long lines at pain clinics, out of state license plates, questionable clients, security guard(s) in the parking lots, and signs stating cash payment only." *Id.* The DEA also asked Actavis to take a "serious look at their quota request, review their suspicious order monitoring system, visit their customers to review their suspicious order monitoring systems" among other things. *Id.* Actavis CEO Boothe refused the request. *Id.* Allergan argues that since the DEA "never took" any action against Actavis, and because Baran testified that the DEA was "very impressed" with Actavis's new SOM program, everything about the meeting should be ignored. Mnf. Opp., p. 44. Yet Allergan fails to note that within three months of that meeting, Watson bought Actavis and reverted to Watson's own inadequate system as of January 2013. Ps' Compliance MOL, pp. 68-69..

Accordingly, Allergan and Actavis have failed to raise a triable issue of fact refuting Plaintiffs' assertion that they failed to comply with their CSA duty to block shipment of, and investigate, suspicious orders.

H. McKesson Fails to Create a Disputed Issue of Fact.

1. McKesson Failed to Maintain a System to Detect Suspicious Orders.

McKesson acknowledges that prior to May 2007, it solely monitored the purchases of controlled substance through its "Section 55" policy, under which McKesson produced daily and monthly reports that documented retrospective sales of controlled substances that exceeded three times the monthly average for a Schedule II or III controlled substance. Dist. Opp., p. 30. McKesson's own regulatory employees have admitted this system did not flag true suspicious orders.[70] Moreover, Plaintiffs provided evidence that McKesson conceded in January 2006 that its Section 55 policy had not been flagging extremely large orders to internet pharmacies because McKesson *did not track* the sale of generic drugs for SOM purposes under that system.[71] Defendants do not refute this evidence in their Opposition. Thus, it is undisputed that prior to 2006, McKesson was not "operat[ing] a system [that would] disclose to [it] suspicious orders of [generic opioids]," in violation of the CSA.

McKesson also failed to comply with its reporting obligations. It claims that, prior to 2008, it submitted daily and monthly "excessive purchase reports" to the DEA. Dist. Opp., pp. 29-30 & n.57. But the DEA has clearly stated that submitting such reports *does not* satisfy a registrant's reporting obligations under the CSA. Ps' Ex. 308 at 980-81 ("Daily, weekly, or monthly reports submitted by a registrant indicating 'excessive purchases do not comply with the requirement to report suspicious orders, even if the registrant calls such reports 'suspicious order reports.'"). Even after 2008, McKesson did not comply with its reporting obligations. McKesson erroneously claims that it was only required to report orders for which it had "a 'high degree of confidence' that there

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[70] Ps' Compliance MOL, p. 79 (citing Ps' Ex. 240 and Hilliard Tr., Dkt. #1963-1, at 176:8 – 176:22).

[71] Ps' Compliance MOL, p. 80 (citing Ps' Ex. 242 (1/06 internal memo) at *877-78).

was a risk of diversion." Dist. Opp., p. 38. This is not an accurate description of its reporting duties under the CSA. 21 C.F.R. § 1301.74. McKesson's use of this faulty standard is consistent with the lack of suspicious order reporting by McKesson in the Counties and nationwide.[72] McKesson also argues that its "reporting to ARCOS of all controlled substance distribution of opioids defeats any claim that McKesson knowingly concealed any suspicious orders from [the] DEA." Dist. Opp., p. 39 & n.77. But the cases McKesson cites are entirely distinguishable.[73] Accordingly, McKesson has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to report all suspicious orders to the DEA.

2. McKesson Failed to Block Suspicious Orders.

McKesson expressly acknowledges that it did not routinely block suspicious orders prior to 2008. Dist. Opp., p. 31. It claims it was not legally obligated to do so under the CSA and its regulations during that time period, but that argument is without merit for the reasons discussed above. *Supra* at § I. McKesson also claims that DEA knew of and consented to this practice prior to 2008. Dist. Opp., p. 31. This assertion is both factually inaccurate and not sufficient to create a fact issue as to whether McKesson violated the CSA.[74]

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[72] See, e.g., **Ps' Ex. 556** [MCKMDL00409453]; **Ps' Ex. 523** [MCKMDL00355350]; **Ps' Ex. 557** [MCKMDL00478912]; **Ps' Ex. 558** [MCKMDL00616425]; **Ps' Ex. 559** [MCKMDL00616426].

[73] *See Universal Health Services, Inc. v. U.S.*, 136 S. Ct. 1989, 2003–04 (2016) (*qui tam* case; noting that evidence that the government "regularly pays a particular claim in full despite actual that certain requirements were violated, and has signaled no change in position" is relevant to evaluating *materiality* under the *False Claims Act*); *U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (*qui tam* case; holding "that the government's knowledge of facts underlying an allegedly false record or statement can negate the scienter *required for [a False Claims Act] violation*") (emphasis added); *U.S. v. Pendergraft*, 297 F.3d 1198, 1209 (11th Cir. 2002) (civil litigants' attachment of false affidavits to motion mailed to opponent in an attempt to coerce, which falsely accused opponent of making threats, did not constitute a scheme to defraud within meaning of the mail-fraud statute, because although litigants may have intended to cause fear, the false accusations in the affidavits concerned the opponent's own conduct, and thus litigants knew that the opponent would not deceived and could not have had the intent to deceive).

[74] McKesson claims that, prior to 2008, the DEA "knew that McKesson . . . was not routinely blocking orders that met the regulatory definition of 'suspicious orders,' and approved this practice as part of its periodic audit process." Dist. Opp., p. 31. McKesson also claims the DEA had approved of "ABDC's [SOM] system—a system materially similar to McKesson's---despite the fact that ABDC's pre-2008 system similarly did not block suspicious orders at that time." *Id.* But if these assertions were true, the DEA would have had no reason to meet with McKesson in early 2006 and criticize McKesson for filling suspicious orders from various internet pharmacies. Ps' Ex. 242 (1/06 internal memo). Additionally, the DEA would not have

(footnote continues on next page)

McKesson also claims that its pre-2008 "Section 55" system required "employees to review controlled substances orders 'before filling' and requir[ed] order fillers 'to report to management any unusual purchase request before orders are filled." Dist. Opp., p. 30. However, this claim is readily refuted by the testimony of Blaine Snider, Distribution Center Manager for McKesson's New Castle Distribution Center. Mr. Snider testified that extra due diligence at the distribution center level was to reduce "fat finger" orders or orders that clearly were mistakes, but otherwise the practice was to fill all orders that were placed. Snider Tr., Dkt. #1970-25, at 70:14 – 71:16, 77:3 – 78:4.

Moreover, McKesson's inflated thresholds and lax standards for increasing those thresholds ensured that very few orders were ever blocked. From May 2008 to June 30, 2018, McKesson filled 772,976 opioid orders in the Counties. Rafalski Rep., Dkt. #2000-22 at p. 80 n.311. During that same time period, McKesson blocked only 2,907 in those Counties. **Ps' Ex. 557** [MCKMDL00478912]; **Ps' Ex. 558** [MCKMDL00616425]; **Ps' Ex. 559** [MCKMDL00616426]. McKesson claims that Plaintiffs lack sufficient examples of its lax threshold increases, especially in the Counties, but that is not so. Whitelaw Rep., Dkt. #2000-26, at pp. 55-59, 90.[75] McKesson's threshold warnings only served as an additional layer to ensure few orders would ever be blocked. **Ps' Ex. 560** [MCKMDL00543971] at *972; Whitelaw Rep., Dkt. #2000-26, at pp. 84-85.

Independently, McKesson's lack of due diligence records further demonstrates that blocked orders were not being properly investigated. The due diligence files produced by McKesson for its customers in the Counties up until January 2014 spanned only approximately 460 pages (MCKMDL00496212-305; MCKMDL00555448-744; MCKMDL00568207-281). This perhaps is not surprising, as McKesson internally acknowledged that its regulatory affairs directors did not have

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alleged—and McKesson would not have agreed to settle—various claims in 2008 concerning multiple distribution centers filling suspicious opioid orders. **Ps' Ex. 522**]MCKMDL00337001]. This evidence demonstrates that DEA did not view McKesson as being compliant with its responsibilities under the CSA.

[75] McKesson also repeatedly focuses its arguments on matters related to causation in an effort to distract from the overwhelming evidence of long-standing CSA non-compliance. These arguments completely miss the point. The elements for which Plaintiffs seek *partial* summary judgment relate to duty and breach. Therefore, whether McKesson's whole compliance failures caused Plaintiffs' harm and the proper damages for that harm are not at issue in these motions.

sufficient time to conduct proper due diligence. **Ps' Ex. 561** [MCKMDL00634329] at *331. Given the lack of supporting diligence records, it is clear that pharmacies that met their monthly threshold—and thus were blocked under McKesson's SOM system—were simply able to continue ordering unfettered once a new month began without any intervening due diligence being conducted by McKesson. As Plaintiffs' expert, James Rafalski, notes, this practice is contrary to the CSA and leads to a pattern of uninvestigated suspicious orders. Rafalski Rep., Dkt #2000-22, at p. 80 of PDF.

Accordingly, McKesson has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duties to identify suspicious orders.

I. Cardinal Fails to Create a Disputed Issue of Fact.

Cardinal similarly failed to maintain a system capable of detecting suspicious orders as defined by the CSA and failed to halt shipments of orders it knew to be suspicious. In their motion, Plaintiffs present evidence that, prior to at least 2008, Cardinal did not have a SOM system in place that would detect all suspicious orders. Ps' Compliance MOL, pp. 71-72. In its Opposition, Cardinal does not directly dispute this, although when discussing its pre-2008 *reporting* conduct, it states that its Ingredient Limit Reports (ILRs) "identified orders that exceeded a predetermined monthly limit for that pharmacy[,]" and its "Excessive Order reports identified orders that reflected unusual patterns/frequency/size of ordering, based on the first-hand knowledge of those patterns by the distribution center employees who filled them." Dist. Opp., p. 20. But Cardinal provides no evidence that these reports allowed it to identify suspicious orders in real time (*i.e.*, before they were shipped). As noted in Plaintiffs' motion (Ps' Compliance MOL, p. 72), Cardinal's own consultant explained when it audited Cardinal's SOM system in December 2007 that these types of retrospective reports are insufficient to comply with its identification duty under the CSA:

> An additional concern with the Phase I system relates to the ability of the system to track deviations in individual ordering patterns. *This requirement is specifically addressed in the regulation*. This was brought to the attention of Mr. Reardon during an on site interview on December 21st and he indicated that Cardinal could discern this information from the "ingredient limit report" (*and thus this requirement was not further incorporated in the SOM system*). Cardinal's "ingredient limit reports" are based upon

> historical information and *are not sufficient to monitor deviations in ordering patterns on a real time basis*. We believe *real time analysis is required*.

Ps' Ex. 219 at *962 (emphasis added). Prior to 2008, Cardinal's SOM system was not designed to identify all suspicious orders in real time. Accordingly, the undisputed evidence demonstrates that Cardinal failed to comply with its CSA duty to identify suspicious orders during that time period.

Moreover, Cardinal concedes in its Opposition that it did not adopt a "do not ship" policy until after January 2008. Dist. Opp., p. 22. A January 2008 audit report on Cardinal's SOM system, prepared by Cardinal's outside consultant, noted: "An additional regulatory deficiency associated with the Phase I system is that an order that is 'blocked' as being possibly suspicious is simply reduced to the threshold limit and filled." Ps' Ex. 219 at *961. Indeed, Cardinal's 30(b)(6) witness testified that, at the time of the deposition, Cardinal did not have knowledge of what actions it took to implement policies and procedures to comply with the DEA's September 27, 2006 letter, until sometime in late 2007 or 2008. *Id.* at 292:11-295:16. No more is required to find that Cardinal failed to comply with the CSA in that period.[76]

Cardinal excuses its blatant failure to report suspicious orders by claiming that, until 2007, the DEA approved of the use of monthly ILRs to satisfy the CSA's reporting requirement. Dist. Opp., pp. 19-21. But Cardinal's response omits critical evidence with respect to its purported guidance from the DEA approving the use of ILRs. Cardinal admits that it relied on correspondence from then Acting Chief of DEA Diversion Operations Section, Thomas Gitchel, stating that the Suspicious Order Monitoring system developed by NWDA in the 1980's was merely a "framework," not a comprehensive system that would satisfy the CSA. Dist. Opp., pp. 20-21. Cardinal ignores, however, Chief Gitchel's clear advisory in that letter that such "after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders. The

[76] Cardinal argues claims that it did not learn of the requirement to stop shipments of suspicious orders in late 2007, but the argument is contrary to the testimony of its 30(b)(6) deposition designee, Jennifer Norris. She testified that Cardinal received the September 2006 "Dear Registrant" letter from Joseph Rannazzisi reminding Cardinal Health that it has a duty to stop shipment of suspicious orders. *See* Norris Tr., Dkt. #1968-20, at 135:10-16.

DEA has interpreted 'orders' to mean prior to shipment." Ps' Ex. 5. According to the very letter Cardinal cites as support for using the ILR system, this method does not, in fact, satisfy Cardinal's duty to report suspicious orders pursuant to the CSA, because under Cardinal's ILR system, the orders identified were already shipped *before* Cardinal reported them. Thus, there is no genuine issue of this material fact that Cardinal knew its ILR program was not compliant on its own.[77]

J. ABCD Fails to Create a Disputed Issue of Fact.

1. ABDC Provides No Evidence that Its SOM Programs Complied with the CSA.

Plaintiffs' motion offers testimonial admissions from Eric Cherveny, ABDC's Director of Diversion Control and Security, Corporate Security and Regulatory Affairs, which show that, prior to 2007, any due diligence investigations of suspicious orders only occurred *after* ABDC shipped those suspicious orders to its customers. Ps' Compliance MOL, p. 91. ABDC does not oppose, let alone address this fact in its Opposition. Dist. Opp., pp. 41-52. Nor does ABDC offer any argument or evidence to suggest that its conduct was compliant with the "no-shipping duty" articulated in *Masters*, 861 F.3d at 212-213.[78] Instead, ABDC rests its entire defense on its contention that (1) the DEA pre-approved its SOMS in 1998, and again between 2001-2003; and (2) ABDC received a "certificate of appreciation" in 2004 for its assistance in training DEA diversion investigators. Dist. Opp., pp. 41-45. For the reasons discussed in § II.J.2 below, this evidence, even if accurately characterized (which Plaintiffs dispute), is not sufficient to create a fact issue precluding summary judgment on ABDC's violation of the no-shipping duty.

Further, ABDC does not dispute that the April 19, 2007 Order to Show Cause (the "OSC") issued against its Orlando distribution center arose, at least in part, from ABDC's practice of

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[77] Cardinal also knew its failure to report suspicious orders allowed diversion to simply be displaced, rather than stopped. **Ps' Ex. 562** [CAH_MDL2804_03191401] at P1.3650.28 ("There is a 'cockroach' effect happening where if we terminate a 'bad' customer based on evidence of potential diversion, those customers will scatter to "good' pharmacies.").

[78] In fact, ABDC provides no discussion about *Masters* other than to note in passing that Plaintiffs' interpretation of the law is "not correct." Dist. Opp., p. 41.

violating the "no-shipping duty."[79] ABDC thus establishes no disputes of fact regarding its pre-2007 practice of violating the "no-shipping duty." Plaintiffs' summary judgment motion as to ABDC's pre-2007 conduct should accordingly be granted, as a matter of law. ABDC also offers no evidence to create a factual dispute with respect to whether its post-2007 conduct violated the CSA's "no-shipping duty." First, ABDC argues the DEA approved its SOMS in 2007 after suspending the license of its Orlando distribution center, but that argument fails for the reasons discussed below (*infra* at § II.J.2). Second, ABDC argues that two designated experts expressed approval of ABDC's SOMS based on its formal, written policies, but ABDC provides no evidence to dispute that those policies were not implemented.[80] A system that is not implemented is the same as having no system at all. ABDC misleadingly offers select excerpts of testimony from its experts Robert Buskey and Seth Whitelaw to argue its SOMs met minimal standards (Dist. Opp., pp. 49-52), but neither Mr. Buskey[81] nor Mr. Whitelaw[82] address the failed implementation of ABDC's SOM policies.

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[79] In its Opposition, ABDC merely argues the OSC did not "focus" on its shipping of suspicious orders. Dist. Opp., pp. 45-46. ABDC's point is unremarkable given the laundry list of ABDC's violations cited by the DEA in the OSC. Nor does ABDC dispute the fact that, as a result of the OSC, ABDC finally agreed to stop shipping suspicious orders before due diligence investigations reveal they are unlikely to be diverted into illegal channels. *Id.* Critically, ABDC does not, and cannot, explain why the DEA issued an OSC and suspended the license of its Orlando facility if the DEA pre-approved its SOMS back in 1998. *Id.*

[80] Plaintiffs' moving papers demonstrate—through documents produced by ABDC and testimony from ABDC's own employees—that ABDC's due diligence policies were not actually applied and thus, ABDC failed to comply with the CSA. Ps' Compliance MOL, pp. 94-96. A 2016 "CSRA 590 Validation Project" indisputably confirms that ABDC had no due diligence information on file for large swaths of its customers. *Id.* at p. 95. By 2017 (10 years after its "new diversion control program" purportedly was implemented), ABDC's internal documents revealed that only about 10% of the required information for a substantial amount of its customers identified as deficient had even been *collected*, let alone reviewed. *Id.* By 2018, only about 60% of those deficiencies had been remedied. *Id.* ABDC's Opposition underscores the acute importance of this fact, by noting ABDC's efforts to collect and analyze information about its customers comprise *two thirds of its entire diversion control program*. Dist. Opp., p. 46 ("ABDC's new diversion control program had three pillars: (1) *new customer due diligence*; (2) an order monitoring program that flagged orders of interest and were reviewed by a trained diversion control team member; and (3) *ongoing customer due diligence*.") (emphasis added).

[81] ABDC claims that Mr. Buskey opined that ABDC's 2007 SOMS exceeded minimum statutory and regulatory requirements. *Id.* at pp. 49-50. ABDC, however, offers no statements, opinions, or other conclusions from Mr. Buskey that address the failed *implementation* of those SOMS policies, or the fact that, as of 2017, ABDC was missing the requisite "Know Your Customer" information for a significant portion of its customers. In addition, and as explained in Plaintiffs' motion, Mr. Buskey's opinion is based on an interpretation of the CSA and "no-shipping duty" that is at odds with the official pronouncements of the DEA, and with the most recent pronouncements and enactments of Congress. Ps' Compliance MOL,

(footnote continues on next page)

ABDC addresses the failures of its due diligence program by claiming "DEA did not require that ABDC have Form 590 information for every customer," no DEA "best practices" regarding what methodology used has been issued, and collected information possibly "had not been maintained in the file or lost." Dist. Opp., p. 51. All three justifications are red herrings.[83] Critically, and as noted above, ABDC expressly acknowledges that its post-2007 due diligence policy for new and existing customers comprises *two-thirds of its entire diversion control program*. Dist. Opp., p. 46. Thus, if ABDC's diversion control program hinged on its ability to review "Know Your Customer" information from its new and existing customers, collecting only 10% of that information from a substantial amount of its customers by 2017 is an objectively failed system, by any legal measure. Put another way, a due diligence program devised in 2007 that is missing key information for a substantial amount of customers by 2017 is the same no due diligence program at all. No amount of out-of-context statements from experts or sleight-of-hand legal arguments can change that. ABDC's ability to remedy only about 60% of the missing information by 2018 reveals the system is still materially broken. In keeping with this factual reality, ABDC offers no evidence to create a triable issue of fact on this point.

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pp. 95-96. Mr. Buskey's statements offered in ABDC's Opposition are accordingly irrelevant and do not address or otherwise challenge the facts offered in Plaintiffs' Motion.

[82] ABDC offers an excerpt of Mr. Whitelaw's testimony for the proposition that ABDC's SOMS met "the minimums" and "the basics that they had to do to get by." Dist. Opp., p. 50, n.142. Just like for Mr. Buskey's statements, however, ABDC offers no statements, opinions, or other conclusions from Mr. Whitelaw that address the failed *implementation* of those SOMS policies. ABDC omits from its brief the fact that when specifically asked whether ABDC acted "as a responsible and reasonable distributor as to their SOMS and anti-diversion program," Mr. Whitelaw replied, "I would argue that they were not reasonable." Whitelaw Tr., Dkt. #1972-7, at 1000:14 – 1001:3. In addition to the fact that ABDC failed to provide Mr. Whitelaw's full statement, the partial statement ABDC did offer does not address or otherwise challenge the fact that ABDC had not actually implemented its due diligence policy. The statement offered is accordingly irrelevant, and does nothing to manufacture a dispute of fact to defeat Plaintiffs' motion.

[83] Whether DEA required ABDC to have such information for every customer is not at issue. Plaintiffs also do not argue that ABDC is required to have Form 590 information for every customer. Nor do Plaintiffs argue that ABDC's due diligence failures ran afoul of specific DEA "best practices" guidelines. Lastly, ABDC's admission that some due diligence files may not have been maintained, or may have even been lost altogether, only supports Plaintiffs' point that the implementation of ABDC's due diligence policy was an objective failure.

While not addressed by the deposition excerpts offered in its Opposition, ABDC's failed implementation of its due diligence policies *is* directly addressed by a third-party consultant analysis commissioned by ABDC. In August 2015, ABDC voluntarily engaged an outside consultant FTI Consulting, Inc. ("FTI") to review its order monitoring system. FTI issued a report documenting the findings of an audit of ABDC's compliance activities. **Ps' Ex. 563** [ABDCMDL00274105]. The FTI report disclosed numerous problems, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies, and communications break-downs. *Id.* The report specifically highlights deficiencies in ABDC's implementation of a policy "centrally tracking and documenting the customer due diligence files and ongoing monitoring activities." *Id.* at *115.[84]

ABDC also does not deny that it shipped suspicious orders after 2007 without having conducted the requisite due diligence to ensure those orders were unlikely to be diverted into illegal channels. Dist. Opp., p. 51. Indeed, Plaintiffs point out multiple specific orders ABDC flagged as suspicious and shipped anyway, without having conducted any sort of due diligence investigation. Ps' Compliance MOL, p. 94. In response, ABDC only argues (1) its transactions are "more entangled than it appears from Plaintiffs' description," (2) it is unclear whether the suspicious orders were actually shipped, and (3) there is no evidence of injury arising from each of these shipped orders. Dist. Opp., p. 51. First, ABDC's nonsensical argument that the transactions are somehow "entangled" is unsupported by any evidence at all, and includes no explanation as to what that actually means, or how that purports to contradict Plaintiffs' evidence. Second, as pointed out in Ps' Exs. 299 and 300 in support of its moving papers, the flagged and shipped orders share the same transaction numbers, which are even identified in Plaintiffs' brief, so any purported confusion by

[84] In addition to the report, for various areas within the company, including Diversion Control, a forty-five page chart discussed "findings & observations," "Gaps & Risks," and "Recommendations." **Ps' Ex. 564** [ABDCMDL00250024]. Notably, a "Gap & Risk" concerning ABDC's Diversion Control program included "[r]egulatory obligations related to diversion control." *Id.* David May, ABDC's Senior Director of Diversion Control, testified that in response to the report, ABDC took no actions and made no changes to its diversion policies or procedures. May Tr., Dkt. #1966-14, at 149:2-5. Again, ABDC offers no evidence to contradict the fact that it failed to actually implement its diversion control policies and procedures.

ABDC cannot be taken seriously. Ps' Compliance MOL, p. 94. Third, as to evidence of injuries arising from those orders, Plaintiffs note that they are not seeking summary judgment on causation and also refer ABDC to its summary judgment briefing on causation regarding injuries arising from those orders.[85] ABDC thus offers no evidence or viable counterargument to create a triable issue of fact on this issue. Accordingly, the undisputed evidence establishes that ABDC failed to comply with its CSA duty to block shipment of, and investigate, suspicious orders.

2. ABDC Fails to Create an Issue of Fact Concerning DEA Approval of Its Policies.

ABDC relies almost entirely on its contention that (1) the DEA pre-approved its SOMS in 1998, and again between 2001-2003, and (2) ABDC received a "certificate of appreciation" in 2004 for its assistance in training DEA diversion investigators. Dist. Opp., pp. 41-45. But, as discussed above, any purported DEA pre-approval of ABDC's system violates federal statutes and regulations. *Supra* at § I.F. Therefore, any such "approval" can and must be set aside and disregarded by the Court. But in any event, ABDC's purported evidence does not establish DEA approval of its programs.

ABDC contends that the DEA pre-approved its SOMS in 1998, when ABDC was shipping suspicious orders to its customers *before* reporting those orders to the DEA. Dist. Opp., pp. 42-45. A review of ABDC's internal documents, however, reveals that any DEA pre-approval at that time was actually based on an agreement that ABDC comply with the no-shipping duty. Specifically, in ABDC's February 1, 1999 "Suspicious Order Reporting Policy and Procedures" sheet, ABDC admits that, under the policy developed "*in conjunction with DEA Headquarters* in Washington, D.C.," if an order is found to be suspicious, its employees "must contact DEA to *report the order before actually shipping* the merchandise." **Ps' Ex. 565** [ABDCMDL00478320] (emphasis added). As acknowledged by ABDC's own ex-DEA consultant, Michael Mapes, "that's not what the company was doing once they'd been bought out by Amerisource." Mapes Tr., Dkt. #2173-40, at 458:7-

[85] *See* Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation, Dkt. #2203.

459:20. ABDC's own documents thus indicate that the agreement reached with the DEA specified that suspicious orders must be reported to the DEA *before* they are ever shipped. Notwithstanding a subsequent hearsay statement offered by Thomas Provoznik (Dist. Opp., p. 44), with no foundation, ABDC offers no direct, admissible evidence to contradict this fact.

Even if the DEA did pre-approve ABDC's SOMS without no-shipping component (it did not), that approval fails to create a triable issue of fact. As discussed above, an administrative agency's purported pre-approval of conduct cannot exempt an entity from clear violations of a law. *Supra* at § I.F. ABDC relies on a 1998 letter and a 2004 "certificate of appreciation" to argue that, despite violating the CSA, its conduct was legal. But ABDC offers no authority to support that claim because none exists.

K. The Remaining Distributors Similarly Create No Disputed Issues of Fact.

1. HBC/Giant Eagle Provides No Evidence that It Complied with Its CSA Duties.

Instead of providing documentary evidence demonstrating that, prior to August 2014, HBC (or Giant Eagle) implemented a system that identified suspicious orders (*i.e.*, orders of unusual size, orders deviating substantially from a normal pattern, *and* orders of unusual frequency) as required under the CSA, HBC/Giant Eagle relies almost exclusively on the vague and self-serving testimony of their own employees. Dist. Opp., pp. 96-101. This evidence is insufficient to create a fact issue precluding summary judgment.[86]

For example, Defendants claim that "[f]rom day one, Giant Eagle had its warehouse employees closely monitor orders and, because these employees were 'attuned to the normalcies' of orders coming from Giant Eagle pharmacies, if they saw aberrations, they would bring it to the attention of warehouse supervisors who would begin an investigation."[87] But HBC's purported use

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[86] *See MJR Intern., Inc. v. Am. Arb. Ass'n*, 596 F. Supp. 2d 1090, 1099 (S.D. Ohio 2009) ("[S]elf-serving, conclusory assertions in deposition testimony, without record support, are insufficient to support or oppose a motion for summary judgment."); *Deebs v. Alstom Transp., Inc.*, 346 Fed. Appx. 654, 656 (2d Cir. 2009) (unpublished) (affirming grant of summary judgment against plaintiffs where "plaintiffs rel[ied] almost exclusively upon their own deposition testimony in order to support their claims").

[87] Dist. Opp., p. 100 (quoting Durr Tr., Dkt. #1961-20, at 90:8 -91:7, 92:12 – 93:8).

of its warehouse employees in SOM monitoring of its 200 customer-pharmacies is an absurd proposition. Defendants offer no instance where such monitoring did anything, including no instances of delayed/prevented shipping or further due diligence.[88]

The evidence clearly demonstrates HBC/Giant Eagle failed to comply with their identification duties under the CSA. Ps' Compliance MOL, pp. 132-39.[89] Indeed, the State of Ohio Board of Pharmacy found that Giant Eagle's system of detection and diversion was inadequate to detect extensive pharmacy staff diversion over a twenty (20) month period.[90] That system of diversion detection and deterrence differs in no way from the flawed system Giant Eagle/HBC employs across HBC's 200 pharmacy-customers. Defendants also argue that there is no evidence that Giant Eagle was a source of diversion. Not so. HBC admits to knowing that theft occurred within Giant Eagle pharmacies.[91] Moreover, in 2013, the federal government secured guilty pleas in

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[88] As Plaintiffs note in their motion, HBC admits in its written discovery that it never trained these employees (or other employees) regarding diversion. Ps' Compliance MOL, p. 134. Also noted in the motion, HBC's warehouse supervisor could not recall warehouse employees receiving any specific training to identify suspicious orders. *Id.*

[89] In their Opposition, Defendants state that certain statements regarding HBC in Plaintiffs' Compliance MOL "rely on footnotes that reference documents or testimony that provide absolutely no support for the allegedly 'undisputed facts' asserted above it." Dist. Opp., p. 94 n.247. On closer review, Plaintiffs now realize that they had mistakenly cited page ranges from the rough-draft depositions instead of those depositions' final transcripts. The following are the corrected page ranges for those citations: (i) Ps' Compliance MOL, p. 136 n.437: "Tsipakis Tr., Dkt. #1971-12, at 114:10 – 116:17; Mollica Tr., Dkt. #1968-5, at 237:4-13; Millward Tr., Dkt. #1968-3, at 186:21 – 187:6; *but see* Millward Tr., Dkt. #1968-3, at 266:11 – 268:6"; (ii) Ps' Compliance MOL, p. 138 n.445: "Tsipakis Tr., Dkt. #1971-12, at 213:8-11, 255:24 – 256:23"; (iii) Ps' Compliance MOL, p. 138 n.446: "Tsipakis Tr., Dkt. #1971-12, at 141:3 – 142:11."

Additionally, the citation in Ps' Compliance MOL at p. 134 n.429 should have been cited on the following page (p. 135) in support of the first sentence "HBC's thresholds were also deficient." The correct citation for n.429, HBC admitting that the threshold report was for "total shipped quantities," is: Tsipakis Tr., Dkt. #1971-12, at 141:3 – 142:11, 215:6-21.

[90] *See* Plaintiffs' Memorandum in Opposition to Defendant HBC's Motion for Summary Judgment, Dkt. #2178, at pp. 4–5 (discussing *In the Matter of Giant Eagle #4098*, Docket Number D-110714-197, State of Ohio Board of Pharmacy Mins, Dec. 5–7, 2011, "Settlement Agreement with Board of Pharmacy").

[91] Mollica Tr., Dkt. #1968-5, at 209:6-22. One Pharmacy District Leader employed by Defendant found that several instances within a single month's narcotic audit should have been reported to DEA officials because of unexplained missing narcotics at Giant Eagle pharmacies. Bencivengo Tr., Dkt. #1959-1, at 120:21–121:8, 123:25–125:13, 135:23–136:9, 137:1–9, 139:7–23, 142:13–143:9. No records of such disclosure or additional investigation on those unexplained missing narcotics are in the production.

this District on indictments accusing defendants of submitting fake prescriptions to a Giant Eagle pharmacy and successfully obtaining opiates at issue.[92]

Accordingly, HBC and Giant Eagle have failed to raise a triable issue of fact refuting Plaintiffs' assertion that they failed to comply with their CSA duties to identify suspicious orders. HBC and Giant Eagle similarly do not dispute that they were unable to automatically stop orders from shipping to its customers which exceeded its threshold monitoring system. Moreover, HBC's 30(b)(6) representative admitted that HBC had no policy or procedure in place to halt shipment of a flagged order pending an investigation:

> Q: . . . . So my question is whether or not the orders are shipped, whether or not there's a policy or a rule, a procedure, that requires the orders to not be shipped until somebody from procurement looks at it and says, oh, that's a false positive, oh, there's a justification for that. Is there a policy, procedure or rule in place that does such?
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> A: No.[93]

Accordingly, the undisputed evidence establishes that HBC/Giant Eagle failed to comply with their duty to block shipment of, and investigate, suspicious orders.[94]

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[92] *See United States v. Eppinger et al*, 1:12-CR-134, 2012 WL 6930580, at ¶ 114, 116, 119 (N.D. Ohio Mar. 13, 2012) (indictment, including ¶ 114 Brittany Glass obtaining from Giant Eagle through fake prescription Oxycontin 80mg (90 count); ¶ 116 Louis Eppinger using another to obtain from Giant Eagle through fake prescription Oxycontin 80mg (90 count); and ¶ 119 Louis Eppinger using another to obtain from Giant Eagle through fake prescription Percocet (90 count, no mg listed)). Both of these defendants pled guilty to "conspiracy to possess with intent to distribute Oxycodone." *United States v. Eppinger, et al.,* Case No. 1:12-cr-00134-CAB-3 (N.D. Ohio) at Dkt. No. 141 (1/24/13 Judgment) (showing defendant Brittany Glass pled guilty); *United States v. Eppinger, et al.,* Case No. 1:12-cr-00134-CAB-1 (N.D. Ohio) at Dkt. No. 165 (4/24/13 Order Accepting Plea Agreement and Judgment) (showing defendant Louis Eppinger pled guilty). This Court may take judicial notice of the fact that the Eppinger court entered judgment against these defendants based on their guilty pleas. FED. R. EVID. 201(b); *Embassy Realty Investments, LLC v. City of Cleveland*, 877 F.Supp.2d 564, 571 (N.D. Ohio July 5, 2012).

[93] Tsipakis Tr., Dkt. #1971-12, at 174:15-23. *See also* Ps' Ex. 441 (3/29/16 internal e-mail in which Adam Zakin, Sr. Director, Pharmacy Administration at Giant Eagle, declined to purchase a third-party controlled substance ordering system, stating: "Were you not there? At the end of the day the only thing it did *that our current system would not do*, was stop the orders physically if there was a threshold.") (emphasis added).

[94] As discussed above, *supra* at § I.F, DEA's failure to take action against HCB/Giant Eagle is not evidence that HBC/Giant Eagle was in compliance and does not create a disputed issue of fact for trial.

2. DDM Fails to Provide Evidence Sufficient to Create a Disputed Issue of Fact.

DDM provides no evidence to dispute that either it failed to identify suspicious orders as required by the CSA or that it failed to conduct due diligence before shipping suspicious orders. Instead, DDM make various irrelevant arguments. First, it notes that it distributed opioids to its own pharmacies, rather than third parties. Dist. Opp., pp. 101-102. This is entirely irrelevant to whether DDM violated its duties under the CSA, and DDM provides no legal authority suggesting otherwise. Next, it claims it has never been the subject of a DEA enforcement action or convicted of any crimes related to its opioid products. *Id.* at p. 102. Again, this is irrelevant, for the reasons explained above (*supra* at § I.F) and in Plaintiffs' Memorandum in Opposition to Defendant Discount Drug Mart, Inc.'s Motion for Summary Judgment, Dkt. #2216, at pp. 8-9. DDM further argues that Plaintiffs have not provided any expert testimony that DDM violated the CSA. Dist. Opp., p. 101-102. As discussed below, this is not accurate and, regardless, expert testimony is not required when the breach of duty is so obvious, as it is here. *Infra* at § III.D. Finally, DDM claims that Plaintiffs have not satisfied the causation requirement of their claims. Dist. Opp., pp. 102-103. But Plaintiffs have not moved for summary judgment on the issue of causation; that is a different element of Plaintiffs' claims that they will establish at trial.[95] Accordingly, DDM has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to identify suspicious orders.

3. Prescription Supply Does Not Create a Disputed Issue of Fact.

In its Opposition, Prescription Supply ("PSI") erroneously claims that Plaintiffs have not established that PSI ever received a suspicious order. Dist. Opp., p. 53. This is simply untrue. PSI's 30(b)(6) corporate representative and President, Thomas Schoen, explicitly conceded that PSI received orders fitting the CSA's definition of "suspicious orders," yet failed to report those orders

[95] Moreover, DDM's arguments regarding causation are nothing more than a regurgitation of its failed arguments in its summary judgment. These arguments are without merit, as explained in Plaintiffs' Memorandum in Opposition to Defendant Discount Drug Mart, Inc.'s Motion for Summary Judgment, Dkt. #2216, at pp. 1, 4-6.

to the DEA.[96] [97] In its Opposition, PSI ignores this testimony, instead arguing that the retrospective "Suspicious Order Monitoring Reports" that it submitted at the end of each month were sufficient to satisfy its reporting obligations under the CSA. Dist. Opp., pp. 54-55. But the DEA has clearly stated that these types of reports *do not* satisfy a registrant's reporting duty. Ps' Ex. 308 at *980-81 ("Daily, weekly, or monthly reports submitted by a registrant indicating 'excessive purchases do not comply with the requirement to report suspicious orders, *even if the registrant calls such reports 'suspicious order reports.'* ") (emphasis added).[98] Accordingly, PSI has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to report all suspicious orders to the DEA.

L. Walmart Fails to Create a Disputed Issue of Fact.

1. Walmart Filed to Identify Suspicious Orders.

The undisputed facts demonstrate that, prior to 2011, Walmart neither developed, nor maintained a suspicious order monitoring system. It is undisputed that Walmart did not have a written policy requiring distribution center employees to monitor for suspicious orders prior to 2011. Dist. Opp., p. 62. Walmart blithely asserts that it does not need a written policy. As an initial matter, Walmart's citation to Krista Tongring's expert report for this proposition is incorrect. Ms. Tongring said no such thing and, instead, limited her report to a regurgitation of Walmart's responses to Plaintiffs' Combined Discovery and the testimony of Walmart's corporate designee that amounts to a farcical *post hoc* narrative that it relied on the personal experience and memories of

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[96] Schoen Tr., Dkt. #1970-17, at 183:23 – 184:3 ("Q:…. PSI agrees that if we're looking at the regs and the statute and the code, that there have been suspicious orders which they failed to report in the past, correct? A: Yes."), 182:11-14, 182:21-183:2 ("Q: And we know Prescription Supply has never reported a suspicious order. And is it Prescription Supply's position that's because they never got a suspicious order? A: It depends on how you define a – Q: Suspicious order? A. – suspicious order. If you define it the way it is in the code, we've received them, okay? Q. Yes, sir.").

[97] PSI's argument regarding the analyses of Plaintiffs' experts McCann and Rafalski in identifying flagged transactions is a red herring as PSI unequivocally acknowledged violating its reporting duty by receiving suspicious orders that it failed to report.

[98] Schoen Tr., Dkt. #1970-17, at 128:11-15 ("Q: And assuming that Mr. Rannazzisi is correct and he sent this letter out to everybody, presumptively Prescription Supply would have gotten that, correct? A: Yes.").

untrained hourly associates. But, even accepting that assertion as true and crediting Walmart's self-serving statements, Walmart's so-called unwritten policies did not comply with its CSA obligations at that time.

First, no reasonable fact finder could determine that Walmart met its identification duty by relying on a handful of hourly associates with no training to use only their memories to manually identify orders of unusual size, pattern, and frequency within 340,000 line items per day.[99] Notably, Jeff Abernathy, who was in charge of this manual review, did not even know how many pills were in a bottle. Abernathy Tr., Dkt. #1956-1, at 128:19-25. Walmart next contends that it met its identification duty by way of *monthly* reports generated by is distribution centers to identify suspicious orders. Not so. Walmart's own witness acknowledged that these monthly reports could not be used, and were not used, to monitor daily orders. Hiland 30(b)(6) Tr., Dkt. #1962-30, at 221:21 – 222:5, 295:7-18 (referring to Controlled Drug Stock Exception Reports). Walmart's citation to these documents despite the contradictory testimony of its own employee is further evidence of the *post hoc* narrative designed to obfuscate the truth, namely that Walmart did not have a complaint SOM at this time.

From approximately 2011 until approximately 2015, Walmart implemented what it called a monitoring program to flag certain very large orders of controlled substances.[100] In particular, it flagged orders of 5000 dosage units or more, and orders of more than 2000 dosage units per week if those orders were 30% higher than a rolling 4-week average. *Id.* In other words, orders under 2000 units per week were never flagged, so a pharmacy could order nearly 8000 units per month without ever alerting the system.[101] Even more problematically, if a pharmacy ordered more than 5000 units,

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[99] **Ps' Ex. 566** [WMT_MDL_000006511] ("We average 40,0000 line items per day of controlled substances. We are also interested in possibly including non-controlled because we run a similar program to maintain VAWD accreditation. That would add 300,000 line items per day.").

[100] **Ps' Ex. 567** [WMT Responses to Combined Discovery]; Hiland Vol. I Tr., Dkt. #1962-30, at 269:8-21; 270:7-17.

[101] At this point, Walmart had been running the "over-20 report" (*i.e.*, more than 2000 dosage units) for years. As a result, Walmart used a minimum threshold of 2000 precisely because it would not trigger many

(footnote continues on next page)

Walmart would just reduce ("cut") the order to 5000 and ship it. [102]

Walmart's contentions that a "20-bottle order is not large," and that monitoring by size is completely appropriate, are entirely misplaced. Walmart wholly ignores that under this so-called system, a pharmacy could order 20 bottles (2000 pills) without ever having ordered any opioids in the past. This would clearly be a deviation from the pharmacy's typical ordering pattern and frequency, and would not have been flagged or reviewed. As such, Walmart system during this time was non-compliant insofar as it was limited to size.[103] Moreover, setting aside that Walmart's internal monitoring was woefully inadequate, Walmart pharmacies could also order narcotics from third-parties without Walmart monitoring those orders. Abernathy Tr., Dkt. #1956-1, at 254:2-10. This was especially problematic because a Walmart pharmacy could have orders fulfilled by both Walmart and a third-party at the same time.[104] In other words, a Walmart pharmacy could surpass Walmart's already high threshold simply by ordering opioids directly from McKesson.

Walmart's own documents concede that the above "system" did not comply with federal regulations. For example, in a 2013 "Controlled Substance Risk Assessment" presentation, Walmart admits that it still had not designed (much less operated) a compliant system for suspicious order

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orders. What is more, there were internal suggestions to consider more than a single item number (**Ps' Ex. 568** [WMT_MDL_000009635]), but Walmart ignored these suggestions as it would interrupt business.

[102] Abernathy Tr., Dkt. #1956-1, at 80:2-20. In mid-2012 Walmart also implemented "hard limits." **Ps' Ex. 567** [WMT Responses to Combined Discovery]. Under this rigid formula weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles (*e.g.,* a 40-bottle order was cut to 20 bottles) and shipped. *Id.*; Abernathy Tr., Dkt. #1956-1 at 64:25 – 65:22; *see also* **Ps' Ex. 602** [WMT_MDL_000009807] ("I will continue to research and cut all Oxycodone 30 mg orders over 20 bottles.").

[103] Indeed, Walmart's internal communications acknowledge this fatal flaw. **Ps' Ex. 603**_[WMT_MDL_000009385] ("Flags only identify 'unusual size.'"); **Ps' Ex. 604**_[WMT_MDL_000009158] (email dated Nov. 23, 2014, attaching "Overview of SOM Project Process" identifying regulatory shortfalls).

[104] *Id.* at 245:18-21 ("Q. Walmart had – was doing business with McKesson at the time, right? Its pharmacies were ordering from McKesson, right? A. Yes, sir."); *see also* **Ps' Ex. 605** [WMT_MDL_000041598] (internal Walmart email dated May 3. 2017 from Miranda Johnson to Katrina Jamison, "This is a really important project for our suspicious order monitoring program because *it will reduce the number of orders going directly to McKesson from the pharmacy. Those direct to McKesson orders limit our ability to get fully visibility to what pharmacies order* and this project will be very helpful to us.") (emphasis added).

identification, monitoring, and reporting. **Ps' Ex. 569** [WMT_MDL_000052997]. It noted that the date that it *would* develop such a system was "TBD." *Id.* And in June 2014, Walmart acknowledged again that it lacked a compliant monitoring program. **Ps' Ex. 570** [WMT_MDL_000048100]; **Ps' Ex. 571** [WMT_MDL_000048101].

In 2015 Walmart implemented store-specific thresholds. Hiland Vol. I Tr., Dkt. #1962-30, at 312:7-18. This post-2015 system was identical to the pre-2015 system other than the institution of store-specific thresholds. **Ps' Ex. 567** [WMT Responses to Combined Discovery]. These thresholds were based on the standard deviation of a specific pharmacy's order history for each controlled substance. *Id.* But, they continued to include minimum amounts below which *no orders were flagged under any circumstance* regardless of pattern or frequency. *Id.* Walmart's corporate designee explained that different limits were not implemented because they "didn't make sense for the business."[105] And the limits were high, nearly always remaining at 2000 dosage units per week.[106] This meant that a pharmacy could still, for example, go from ordering ten dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed.

Accordingly, Walmart has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to identify suspicious orders.

2. Walmart Failed to Conduct Due Diligence before Shipping Suspicious Orders.

Walmart shipped numerous suspicious orders to the Counties, choosing to ignore *all* of them.[107] Walmart's contention that Plaintiffs' expert opined that Walmart's overall distribution in

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[105] Hiland Vol. I Tr., Dkt. #1962-30, at 403:24 – 404:5. In other words, these thresholds were for the business, *not* "maintenance of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C. § 823(a)(1), (b)(1); *see also* **Ps' Ex. 568** [WMT_MDL_000009635] ("business intuitively identified the outlier order sizes (90,000, 10,000 etc..) and also decided (from a business sense) that order size 5000 should be a reasonable large cap."). Indeed, as late as 2016, Walmart's SOM decisions were driven primarily by cost considerations as opposed to regulatory compliance. *See, e.g.,* **Ps' Ex. 606** [WMT_MDL_000017434] ("SOM enhancements …*awaiting business decision as cost is extremely high.*") (emphasis added).

[106] Reed Tr., Dkt. #1970-5, at 74:24 – 75:11; Hiland Vol. I Tr., Dkt. #1962-30, at 313:1-13, 316:7-16, 320:4-12.

[107] *See* Plaintiffs' Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs, Dkt. #2218-5, at Exhibit A, p. 11.

both Counties was "*de minimis*" (Dist. Opp., p. 57) is incorrect[108] and factually irrelevant to Walmart's failure to design and implement a compliant SOM program.[109]

Walmart acknowledges that it did not meet its no-shipment duty prior to 2011. Dist. Opp., p. 63. Quite simply, its absurd claim that it was not required to hold flagged orders prior to shipment epitomizes Walmart's failures to meet its CSA obligations. Walmart does not, because it cannot, cite any evidence that it met its no-shipping duty prior to 2011.[110] In contrast, Plaintiffs have cited ample evidence that Walmart did not have a policy (written or unwritten) or practice to hold shipments during the pre-2011 time period. Mr. Abernathy, who was in charge of this manual review process at this time, testified that he was not aware of a policy to hold shipment of suspicious orders. Abernathy Tr., Dkt. #1956-1, at 149:16-20.

Walmart continued to violate its "no-shipping" duty between 2011 and 2015. As discussed above, during that time period, Walmart's monitoring program would flag orders of 5000 dosage units or more. *Supra* at pp. 55-56. But instead of holding and investigating those orders, Walmart would just cut the order to 5000 units and ship it. Abernathy Tr., Dkt. #1956-1, at 64:25 – 65:22, 80:2-20. Moreover, it was not until late 2014 that Walmart's written policies and procedures required a suspicious order to be held until it was verified as appropriate.[111] And, even then, there is

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[108] Walmart claims that Dr. McCann testified that a 1% market share would qualify as a "*de minimis*" amount in the context of distribution market share. That is wrong. Dr. McCann testified that 1% "returns" would be "*de minimis*." **Ps' Ex. 572** (5/10/09 Dr. Craig McCann Dep. Tr. excerpts) at 508:12-510:15. Indeed, in response to counsels' question as to whether "[i]n a data set as large as the one that [he] reviewed concerning the shipments of opioids into Cuyhoga and Summit County, [would he] consider de minimis to be 1 percent," Dr. McCann testified that "[he'd] have to think through the context a little bit. *But in some contexts 1 percent would be de minimis and in other contexts not*." *Id.* In any event, there is no legal authority for the proposition that a 1% market share is a bar to liability.

[109] This case concerns Walmart's failure to properly monitor its distribution of controlled substances, not Walmart's market share. Walmart does not cite a single case for the counterintuitive proposition that *some* wrongful opioid diversion resulting from its failure to design and implement a SOM program is acceptable so long as the offending party does not have a large market share in a particular country.

[110] Here, yet again, Walmart's citation to Krista Tongring's expert report is incorrect. While Ms. Tongring does assert that "when orders were identified for review, they were held during the review process and not shipped to the pharmacy," the testimony that she cites does not remotely support that conclusion. *See* Tongring Rep., Dkt. #1939-32, at p. 6-7, ¶ 5 (citing Hiland Vol. I Tr., Dkt. #1962-30, at 45:10 – 46:2, 209:13 – 212:9, 226:24 – 227:16).

[111] **Ps' Ex. 567** [WMT Responses to Combined Discovery] (citing WMT_MDL_000011107).

no evidence that Walmart actually ever followed this policy.[112] Although daily reports were sent from the Distribution Center to Walmart's headquarters in Arkansas (known as the "Home Office") there is no evidence that anyone at the Home Office ever reviewed even a single one of these reports, much less took any action concerning them. Mr. Abernathy, who prepared these reports, acknowledged that he never recalls the Home Office reviewing or holding any order over the entire period.[113]

Accordingly, no reasonable fact finder could conclude that Walmart complied with its CSA duty to block shipment of, and investigate, suspicious orders prior to 2015.[114]

M. Walgreens Fails to Create a Disputed Issue of Fact.

1. Walgreens Failed to Identify Suspicious Orders.

Plaintiffs present evidence that, prior to 2012, Walgreens did not have a SOM system in place that had the ability to detect all suspicious orders. Ps' Compliance MOL, pp. 113-122. Walgreens did not begin to design such a system until 2008 and did not fully implement it until 2012.[115] Prior to this time, Walgreens's system focused on extraordinary size. Even after implementation, Walgreens's SOM system continued to have significant gaps. Ps' Compliance MOL, pp. 113-122. Walgreens also manipulated the new SOM system to avoid detecting suspicious

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[112] Walmart's statement that it "appropriately leveraged" its pharmacy-level data is belied by its own documents and testimony. It was not until 2014 that Walmart even considered pharmacy level data as part of its ordering monitoring. Reed Tr., Dkt. #1970-5, at 30:3-20. What is more, in September 2010, the DEA admonished Walmart for not having a more intimate knowledge if its pharmacies (customers). **Ps' Ex. 573** [WMT_MDL_000057259].

[113] Abernathy Tr., Dkt. #1956-1, at 61:14-21, 122:24 – 123:23, 138:1-7.

[114] Walmart's claim that the DEA or Verified Accredited Wholesale Distributors ("VAWD") approved its non-compliant SOM systems is wrong. As explained above, The DEA does not certify SOM systems as compliant and "expects that each registrant will review its business model and design a [SOM] system that fits its designed method of distribution." *See* Prevoznik Vol. I Tr., Dkt. #1969-12, at 179:22 – 180:15; Prevoznik Vol. III Tr., Dkt. #1969-14, at 1177:15-19; Rannazissi Vol. II Tr., Dkt. #1969-21, at 466:17-22. The recognition of the need for individualized programs does not absolve a registrant of the obligation to design programs that comply with the CSA.

[115] Ps' Ex. 351 at *818; Ps' Ex. 358; Ps' Ex. 359; Ps' Ex. 360 at *938; Ps' Ex. 361; Bratton Vol. II Tr., Dkt. #1959-10, at 202:16 – 275:8.

orders, raising ordering limits to avoid triggering due diligence obligations and clearing 95% of all requests to override SOM limits.[116]

Walgreens' excessive distribution of opioids reveals the failings of its nominal SOM and CSA compliance efforts. Between 1996 and 2014, Walgreens shipped approximately 133,938,529 dosage units of opioids to its own pharmacies in the Counties.[117] Of those, at least 125,133,525 dosage units were shipped in fulfillment of orders that, under the CSA, were "suspicious" and should never have been shipped.[118] Walgreens has presented no evidence that all of these orders were flagged by any Walgreens's SOM system.

Walgreens's status as a chain pharmacy does not shield it from liability. The CSA requirements for chain and nonchain distribution and dispensing are the same.[119] Indeed, because Walgreens had full visibility into all dispensing related information necessary to reveal red flags and criteria of suspicion, Walgreens might even be viewed as more culpable due to the wealth at data at its complete disposal. Walgreens internally touted its ability to conduct sophisticated "[d]ata mining… across [its] retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive…," though it failed to appropriately incorporate this data into its SOM program to prevent the excessive flood of opioids into Ohio. Ps' Ex. 323; Ps' Ex. 378.

Walgreens takes the position that using a formula as part of its SOM program constitutes automatic compliance with the CSA's requirements to institute effective controls against diversion and report and halt suspicious orders. Walgreens is wrong—and knows it. The DEA told Walgreens in 1988 that simply using a formula in a SOMS program was not sufficient to satisfy Walgreens's obligations under the CSA, specifically instructing Walgreens that after-the-fact reporting was insufficient and that even a system incorporating a formula "is not complete until the

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[116] **Ps' Ex. 574** [WAGMDL00010887] (showing approval rate for threshold requests at 95%+ for FY 2014 and 2015); Ps' Ex. 379 (ability to control workload by adjusting ceilings).

[117] McCann Rep., Dkt. #2000-14, at Appendix 10 at 226 and 856 of 1260.

[118] *Id.* *See also* McCann Rep., Dkt. #2000-14; Rafalski Rep., Dkt. #2000-22.

[119] 21 C.F.R. § 1301.71(a) and 21 U.S.C. § 823(a)(1), (b)(1).

data is carefully reviewed and monitored by the registrant." Ps' Ex. 327. Similarly, the DEA instructed Walgreens again in 2006 that any SOM system, formula based or otherwise, must identify orders based not only on size, but also pattern and frequency. Ps' Ex. 343; Ps' Ex. 344. Walgreens' failure to monitor for pattern and frequency violated the CSA.[120]

Walgreens knew that its failure to institute effective SOM programs and controls against diversion was universal to all of its distribution centers (DCs), as admitted in its 2008 Internal Audit. Ps' Ex. 350. Walgreens admits that the SOM systems and procedures at all of its DCs were the same, including those at the facilities that continued shipping opioids into the Counties.[121] These universal failures were exposed in high relief by the opioid crisis in Florida, and reflected in the 2012 regulatory action and 2013 Memorandum of Agreement and $80 million fine.[122]

The record reveals that the regulatory issues and red flags which led to the Florida regulatory action extended throughout Walgreens's nationwide operations, including in Ohio. For example, in 2012, when Anda analyzed Walgreens's controlled substances sales by state, it observed: "Although we thought FL/GA stores might be more "questionable" than other states, the data has actually shows that this is not the case . . . . On a national level, 21% of Rx's and 24% of pill count are Controlled Substances vs. Non-Controls . . . . FL/GA stores are not necessarily "abnormal". . . . There are other states that have somewhat comparable questionable store

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[120] Walgreens' reliance on Tasha Polster's testimony regarding the effect of "gaps" in Walgreens SOM system is flawed and should not be given weight. Ms. Polster testified that she was not familiar with any iterations of the Walgreens SOM program that predated her becoming director of RX Integrity in late 2012. Polster Tr., Dkt. #1969-10, at 245-248. Incredibly, Ms. Polster also testified that she did not view it as a "gap" in the SOM program that Walgreens permitted its pharmacies to order controlled substances from an outside distributor if Walgreens DC's rejected those same orders. *Id.* at 236-254.

[121] Stahmann Tr., Dkt. #1971-2 at 94-96 (Suspicious Control Drug Report process used for all DCs "nationwide."); Bish Tr., Dkt. #1959-2 at 34-37 (Perrysburg, Ohio DC employees and Woodland, CA DC employees were trained on Schedule II distribution policies and procedures by Jupiter DC, which were uniform across the distribution centers); George Tr., Dkt. #2169-16, at 91-97 (the same SOM related programs regarding dispensing were in place in all fifty states, including Florida and Ohio).

[122] While the admissibility of the 2013 MOA will be more thoroughly addressed in later briefing specific to these evidentiary issues, Walgreens evidentiary objections to the MOA and related documents are not well founded. *See, e.g., United States v. Cohen*, 946 F.2d 430, 435 (6th Cir. 1991) (admitting defendant's consent judgment as a party admission under FED. R. EVID. 801(d)(2)(A)).

percentages . . ."[123] Anda further attached a chart showing that 192 out of 255 Ohio Stores should be red flagged for the high number of controlled substances, including oxycodone, being dispensed.[124] And yet, Walgreens continued to supply these pharmacies and failed to flag and report.[125] Accordingly, it is not surprising that, in February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg, Ohio DC to those issued to the Jupiter, Florida DC,[126] and Walgreens's employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC. Ps' Ex. 337; Ps' Ex. 338.

That Walgreens instituted *some* more robust anti-diversion measures in its pharmacies—such as institution of an updated Good Faith Dispensing policy in 2011 and 2012[127]—*after* the DEA began its investigations and crackdown does not excuse Walgreens from its many CSA violations and failings. Accordingly, Walgreens has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to identify suspicious orders.

2. Walgreens Failed to Conduct Due Diligence Prior to Shipping Suspicious Orders.

Though Walgreens's Opposition discusses various types of purported due diligence, Walgreens did not perform this "due diligence" on the orders Walgreens identified as suspicious based on size in its Suspicious Control Drug Reports. Walgreens does not dispute that it did not perform due diligence on thousands of orders which Walgreens identified as "suspicious" based on

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123 **Ps' Ex. 575** [WAGMDL00774715, WAGMDL00774717, WAGMDL00774718].

124 *Id.*

125 Significantly, in 2011, Walgreens' internal counsel recommended Walgreens intentionally *not* document its own noncompliance. **Ps' Ex. 576** [WAGFLDEA0001890] at *894 ("If these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance.").

126 **Ps' Ex. 577** [WAGMDL00493697]; Ps Ex. 336.

127 **Ps' Ex. 578** [WAGMDL00066600] at *601-630 (presentation and speaker notes outlining updates to GFD policy); **Ps' Ex. 579** [WAGMDL00745752] (updated GFD policy communicated to pharmacy stores until June 2012); **Ps' Ex 580** [WAGMDL00659801] at *808-809 (describing updates to policy in response to DEA investigations and actions in 2011 and 2012); **Ps' Ex. 581** [WAGMDL00049864] at *065 (description of new "target drug" GFD policy in late 2012, specific to some opioids, recognizing irregular treatment of these drugs across Walgreens pharmacies).

their extraordinary volume and then shipped to its stores in the Counties without review.[128] Based on the undisputed record, partial summary judgment is appropriate with respect to these orders.

The record shows that the due diligence conducted on other orders was insufficient as a matter of law to comply with the CSA. For example, Walgreens cites to the testimony of Deborah Bish, the CII function manager at Walgreens's Perrysburg DC, for the proposition that unusual orders were escalated by the DC to a manager for review. However, Ms. Bish could only recall one instance in the entire time she was the CII Function Manager, from October 2002 to present, that she contacted a manager regarding a questionable order.[129] In fact Ms. Bish admitted that due to the volume of orders the DC was simply unable to look at every order.[130] Walgreens also cites to testimony of Rx Inventory manager, Barbara Martin, to support its assertion that Walgreens inventory and loss prevention personnel conducted due diligence prior to 2012. However, Ms. Martin's testimony and related documents reveal that the full extent of the "due diligence" performed on this example of "huge quantities" of oxycodone identified by Walgreens's DC personnel was to provide the number of bottles previously shipped to the store and the district pharmacy supervisor's cell phone number.[131]

Walgreens cites to Ms. Bish's testimony, and that of Jennifer Diebert, another controlled substances manager from the Perrysburg distribution center, claiming their calls to pharmacies to regarding large orders constituted due diligence. However, both Ms. Diebert and Ms. Bish testified that their pharmacy inquiries were confined to checking for typographical errors in the ordering system. Ms. Diebert testified her calls were only to confirm "that the order entered was actually

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128 **Ps' Ex. 582** [E. Bratton 30(b)(6) Deposition Erratum No. 3] ("Walgreens is currently unaware of due diligence that was performed based on an order being flagged in the Chemical Handler's report… Ms. [Barbara] Martin[] testi[fied] that she did not perform due diligence on the reports in question."). *See also* **Ps' Ex. 583** [Walgreens's Second Supplemental Responses to Plaintiffs' Combined Discovery Requests] at p. 12-13. ("Walgreens responds that it has produced over 5,000 Suspicious Control Drug Orders (i.e. Suspicious Order Reports) for the Track One jurisdictions.").

129 Bish Tr., Dkt. #1959-2, at 28:4-10, 89:15 – 91:10; Rafalski Rep., Dkt. #2000-22, at 119.

130 Bish Dep., Dkt. #1959-2, at 455:20-21.

131 Rafalski Rep., Dkt. #2000-22, at 117-119.

what the[] [store] wanted," and not "second-guessing…how much a store should or should not be receiving." Diebert Tr., Dkt. #1961-15, at 146-17. Ms. Bish testified that her calls to pharmacies were simply to "verify" that what they "punched in" was "what they really intended to order." Bish Tr., Dkt. #1959-2, at 481-482, 485.

3. Walgreens' Interactions with the DEA Do Not Create a Disputed Issue of Fact about Its Compliance.

Walgreens attempts to justify its failure to comply with its CSA duties by arguing that the DEA "approved" its use of "multiple of an average" post-shipment extraordinary size reports as its exclusive or primary SOM methods. Dist. Opp., pp. 67-68. However, the very letter Walgreens cites as support for its contention that the DEA approved its SOMs system states "[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the responsibility of reporting excessive or suspicious orders. The[] regulations require that a registrant maintain a system to detect excessive 'orders' rather than sales of controlled substances." Ps' Ex. 327 (emphasis added). Thus, there is no genuine issue of fact that the DEA approved the use of post-shipment extraordinary size reports (*i.e.* the Suspicious Control Drug Order reports).

Walgreens also claims that two DEA audits of its SOM systems create issues of fact about the compliance of those systems. Dist. Opp., pp. 68-70. However, Walgreens has provided no evidence of express approval of its SOMs system from the DEA; it relies solely on the DEA's failure to take action against it. But even if such inaction were evidence of approval (as opposed to a choice about resource allocation)—which it is not—there is no indication the DEA even reviewed Walgreens's SOM program during the 2009 and 2010 inspections Walgreens cites, let alone that the DEA approved Walgreens's post-shipment extraordinary size report SOM system.[132]

[132] Walgreens cites a June 25, 2009 letter from the DEA following an on-site investigation at Walgreens's Perrysburg DC, which noted recordkeeping violations involving both controlled substances and List I chemicals. It appears that the primary areas reviewed during this DEA inspection were record keeping and the "day-gate" in the Schedule II vault. **Ps' Ex. 584** [WAGMDL00493683]. Walgreens also cites an internal email dated 09/08/2010 titled Mt. Vernon DEA Audit, which states "Great news that the DEA just completed their on site review of Mt Vernon and came away without any issues or citing of the operation. Per your call, the review and recap went well for the procedures, inventory and operation surrounding control drugs handled through our DC. Nice work Mt. Vernon team! Dwayne - the on site agents did request that (footnote continues on next page)

N. **CVS Fails to Create a Disputed Issue of Fact.**

Plaintiffs' opening brief described in detail CVS's wholly inadequate reliance on "pickers and packers" to identify suspicious orders from 2006 to early/mid 2009. Ps' Compliance MOL, pp. 123-124. CVS argues that it "supplemented [the Pickers and Packers] system with several additional controls." Dist. Opp., p. 79. First, CVS argues that it only distributed Schedule III hydrocodone combination products ("HCPs"). This is true but meaningless, because CVS had the same obligation to identify HCPs as any other Schedule II or Schedule III drug. Indeed, CVS's cavalier treatment of HCPs was especially pernicious: as Plaintiffs have pointed out numerous times, in a "Drug Fact Sheet," the DEA stated that "[h]ydrocodone is the most frequently prescribed opioid in the United States and is associated with more drug abuse and diversion than any other licit or illicit opioid." Dkt. #812 at pp. 22-23 (quoting DEA Drug Fact Sheet).

Second, CVS claims that it only distributed to CVS pharmacies. Again, this is true but irrelevant. Limiting distribution to pharmacies with a particular sign on the door does nothing to aid in the identification of suspicious orders. CVS does not argue, nor could it, that it relied on its pharmacies to identify their own suspicious orders.

Finally, CVS continues to rely upon the PDMR Viper reports. However, CVS witnesses testified that these reports were *not* designed to determine suspicious orders.[133] Rather, the Viper Report was an aggregate report that showed shipping versus dispensing to determine whether there was a theft of product. Dugger Tr., Dkt. #1961-19, at 104:12-22. CVS's corporate representative confirmed that that Viper Reports were not reviewed before orders for controlled substances were shipped to CVS's pharmacies. Vernazza Tr., Dkt. #1971-15, at 191:22 – 192:12. Accordingly, CVS has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to identify suspicious orders.

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we stop sending them the Suspicious Control Drug disc and information. They stated that we could keep if it we wanted it, but to stop sending it to them[.]" **Ps' Ex. 585** [WAGMDL00387641]. This internal email is certainly no evidence of DEA approval of Walgreens's SOM system.

[133] Vernazza Tr., Dkt. #1971-15 at 191:18-21 ("But the point of this was not to produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA.").

O. Rite Aid Does Not Create a Disputed Issue of Fact.

Rite Aid does not dispute that its distribution system failed to identify a single suspicious order prior to shipment.[134] Yet incredibly it claims that this is not indicative of a failure to maintain effective controls against diversion, but rather shows how effective its distribution system was because it prevented suspicious orders from being placed in the first place. Dist. Opp., pp. 88-89.[135] To the contrary, Rite Aid's distribution system, which was based on a static, blanket threshold for all Rite Aid stores, made it nearly impossible to identify suspicious orders. Ps' Compliance MOL, pp. 128.

In their motion, Plaintiffs identify a number of suspicious orders in the Counties that should have been identified as such by Rite Aid. Ps' Compliance MOL, p. 128. In response, Rite Aid, notwithstanding its vertical integration, attempts to defend itself by drawing an artificial distinction between its distribution and pharmacy operations. Specifically, Rite Aid erroneously contends that Plaintiffs have not actually identified any suspicious orders because Plaintiffs "conflate orders distributed to pharmacies by Rite Aid Mid-Atlantic" with "prescriptions filled by pharmacies." Dist. Opp., p. 85. In so arguing, Rite Aid ignores the obligations it had as a distributor to know its customer and identify many of those same improperly dispensed orders and suspicious orders. All of the examples given by Plaintiff show how Rite Aid had no system to identify and report suspicious orders from pharmacies with inappropriate dispensing, including its own stores. Even

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[134] Rite Aid had a "distribution system" rather than a SOM system. In 2013, recognizing the shortcomings of its distribution system, Rite Aid sought to develop a SOM system in order to "develop effective controls against the diversion of controlled substances[.]" Ps' Ex. 423; Ps' Compliance MOL, p. 132. Rite Aid never adopted this new SOM system because it stopped distributing controlled substances before it could be implemented. Ps' Compliance MOL, p. 132. In its Opposition, Rite Aid claims that the 2013 proposal was simply meant to consolidate its existing SOM systems. Dist. Opp., p. 91. But the testimony of Janet Hart, Rite Aid's director of government affairs, refutes that claim. Hart Vol. I Tr., Dkt. #1962-21, at 254:13 – 264:24 ("Q: Just so I have this clearly, one is the – the cells highlighted in yellow in this document, the activity described is not being done at all at the time in 2013. Correct? A: Correct. Q: And not just by the department head or anything, it's not being done by anyone at Rite Aid. Right? A: That is correct.") (internal objection omitted).

[135] This argument is nonsensical. Rite Aid was a distributor who contributed to the flood of opioids in the Counties and nationally. The argument that Rite Aid had no suspicious orders is like someone claiming he never exceeded the speed limit because he was never given a speeding ticket. Just because Rite Aid did not identify any suspicious orders does not mean that none existed.

when faced with situations where it knew products were being diverted, Rite Aid did not report any of the orders, nor did it adjust its automated ordering system to account for the fact that some of the store's prior sales volume was inflated from diversion. Ps' Compliance MOL, pp. 126-131.

Rite Aid argues that dispensing at Rite Aid pharmacies for an indicted pill mill doctor (Dr. Harper) is not relevant to its distribution activities. But Dr. Harper's activity was prolific (he wrote prescriptions for "hundreds of thousands of [opioid] doses" according to indictment) and his illegal prescribing involved the hydrocodone combination products Rite Aid distributed (*e.g.*, Percocet).[136] Rite Aid was obligated *as a distributor* to identify and stop the orders that were supplying Dr. Harper's customers at Rite Aid stores. Likewise, Rite Aid's suspicious prescriber list is dismissed as having "nothing to do with Rite Aid Mid-Atlantic's obligations as a distributor" because it was related to dispensing prescriptions. Dist. Opp., p. 85. But that is precisely Plaintiffs' point—Rite Aid did not use the information it readily acknowledged identified "suspicious prescribers" to fulfill Rite Aid's obligation to identify and report orders made to meet the needs of those prescribers.

Furthermore, throughout its Opposition, Rite Aid flip-flops on whether dispensing conduct at the pharmacy level is relevant, conveniently choosing to consider dispensing operations when it believes they may support Rite Aid's argument, but drawing an arbitrary line between dispensing and distribution activity when it does not.[137] Rite Aid's hypocrisy clearly can be seen through its arguments about why "it's no surprise" Rite Aid identified zero suspicious orders. Dist. Opp., p. 87. Rite Aid specifically points to the fact that it only distributed to its own stores and that it never distributed to "pill mill doctors" or internet pharmacies. Thus, Rite Aid concentrates on the *dispensing entities* to show why there were no suspicious orders it distributed. Rite Aid cannot

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[136] Ps' Compliance MOL, p. 129; DOJ U.S. Attorney's Office (Northern District of Ohio) 2/13/15 press release, "Akron Doctor Sentenced To 10 Years In Prison For Illegally Prescribing Painkillers, Even After Patients Died," *available at* https://www.justice.gov/usao-ndoh/pr/akron-doctor-sentenced-10-years-prison-illegally-prescribing-painkillers-even-after (last accessed 8/15/19).

[137] Rite Aid and other Defendants have long argued that Plaintiffs cannot connect the distributors with specific incidents of diversion. But when Plaintiffs do exactly that, as Plaintiffs have done here with Rite Aid, Rite Aid claims that the supply of the drugs cannot be connected to diversion because it is dispensing activity.

concurrently argue that its own pharmacies as dispensing entities are not relevant to its failure to identify any suspicious orders as a distributor.

Rite Aid also argues that its patchwork of policies amounted to effective controls against diversion. Yet, the mere existence of some policies does not amount to *effective* controls against diversion. Plaintiffs' response to Rite Aid's summary judgment motion, incorporated herein by reference, shows how the very policies that Rite Aid points to in its Opposition have been found to be deficient as a matter of law.[138] For example, Rite Aid points to the undisputed facts that it was Rite Aid's policy to "cut" orders above its blanket threshold of 5,000 dosage units before shipment and to the existence of its "threshold logs" as evidence of its SOM system. Dist. Opp., p. 88. But Rite Aid's conclusion that these policies and procedures is evidence of effective controls against diversion does not follow. Rather, as established by *Masters,* 861 F.3d at 216-217, the practice of cutting orders or keeping only limited investigative orders are not *effective* controls against diversion.[139]

Accordingly, Rite Aid has failed to raise a triable issue of fact refuting Plaintiffs' assertion that it failed to comply with its CSA duty to identify suspicious orders.

III. ADJUDICATION OF THE SCOPE OF DEFENDANTS' DUTIES AND THEIR COMPLIANCE WILL STREAMLINE THE TRIAL.

Defendants claim that even if they violated the CSA, that fact would not establish any element of Plaintiffs' claims. Dist. Opp., p. 10. They further argue that Plaintiffs are impermissibly attempting to enforce the CSA through private causes of action. Both arguments are wholly without merit. *Id.*

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[138] *See* Plaintiffs' Memorandum in Opposition to Defendant Rite Aid of Maryland's Motion for Summary Judgment ("Ps' Opp. to Rite Aid MSJ"), Dkt. #2185, at pp. 6-7.

[139] Additionally, as explained in detail in Plaintiffs' response to Rite Aid's summary judgment motion, the DEA and other government audits should not be considered for purposes of summary judgment because they are inadmissible hearsay, and, even if the audits are considered, they contradict, rather than support, Rite Aid's contention of government endorsement. *See* Ps' Opp. to Rite Aid MSJ"), Dkt. #2185, at pp. 7-9.

A. Plaintiffs' Common Law Claims Are Neither Preempted Nor an Attempt to Indirectly Enforce the CSA.

Contrary to Defendants' assertions, Plaintiffs are not attempting to enforce Defendants' statutory and regulatory duties. Rather, Plaintiffs are seeking to hold Defendants responsible for conduct that violates state law (and RICO) *as well* as the CSA. The cases cited by Defendants are entirely distinguishable.[140] Defendants also briefly raise their oft-repeated argument that Plaintiffs' common law tort claims are preempted, citing their prior briefing on the issue. Dist. Opp., p. 12 & n.45. This argument is wholly without merit, as explained in Plaintiffs' responses to such briefing, which Plaintiffs incorporate as if fully set forth herein.[141] Moreover, the Court has already rejected this preemption argument when raised by the Manufacturer Defendants in their motion to dismiss. Dkt. #1025 at pp. 52-54; Dkt. #1203 at p. 2.

B. A Determination that Defendants Violated the CSA Will Streamline the Presentation of Plaintiffs' Common Law Claims at Trial.

With respect to Plaintiffs' statutory nuisance claim, Defendants simply reiterate their

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[140] *See Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110, 113 (2011) (addressing whether entities covered by § 340B of the Public Health Services Act, which "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities[,]" "though accorded no right to sue for overcharges under the statute itself, may nonetheless sue allegedly overcharging manufacturers as third-party beneficiaries of" the form contracts through which manufacturers subscribed to the 340B program; court held: "If 340B entities may not sue under the statute, it would make scant sense to allow them to sue on a form contract implementing the statute, setting out terms identical to those contained in the statute. Though labeled differently, suits to enforce § 340B and suits to enforce [the form contract] are in substance one and the same."); *City of Rancho Palos Verdes, Cal. v. Abrams*, 544 U.S. 113, 115 (2005) (holding that individuals cannot enforce limitations on local zoning authority set forth in the Communications Act through a § 1983 action because there was an "express, private means of redress [for those individuals] in the statute itself"); *Alexander v. Sandoval*, 532 U.S. 275, 278 (2001) (addressing "whether private individuals may sue to enforce disparate-impact regulations promulgated under Title VI of the Civil Rights Act of 1964"; plaintiff was not asserting common law claims, but rather seeking to enforce the regulations directly); *Durr v. Strickland*, 602 F.3d 788, 789 (6th Cir. 2010) (holding death row inmate, who argued the use of certain drugs for his execution violated the CSA, FDCA, and associated federal regulations, not entitled to declaratory relief; plaintiff had not asserted common law claims, but rather was seeking to directly enforce the statutes and regulations through a declaratory judgment action).

[141] *See* Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Preemption Summary Judgment Motions, Dkt. #2171; *see also* Dkt. #654 at pp. 114-122. *Compare Loreto v. Procter & Gamble Co.*, 515 Fed. Appx. 576, 579-80 (6th Cir. 2013) (unpublished) (plaintiff's claim that defendant's products were illegal "because their labeling did not comply with the FDCA's requirements" impliedly preempted because the "theory of liability depend[ed] entirely upon an FDCA violation[,]" whereas plaintiff's claims based on defendant's false advertising of its products was not preempted because that "theory reli[ed] solely on traditional state tort law predating the FDCA, and would exist in the absence of the Act").

argument that the CSA and its implementing regulations do not create any duty to maintain effective controls against diversion. Dist. Opp., p. 11. This argument is without merit for the reasons set forth above. *Supra* at § I. Defendants also, in a footnote, attempt to argue that a violation of "federal rules and regulations" does not constitute a violation of "any . . . laws of . . . the United States . . . controlling the distribution of a drug of abuse . . ." under OHIO REV. CODE § 4729.35. First, Plaintiffs have asserted that Defendants violated the CSA, a statute, as well as its implementing regulations. Second, Defendants cite no authority for their proposition that the CSA regulations are not a "laws" of the United States.[142] This is not surprising, as the United States Supreme Court has expressly held that "substantive agency regulations have the 'force and effect of law.' " *Chrysler Corp. v. Brown*, 441 U.S. 281, 295 (1979) (citation omitted).[143]

Defendants' arguments as to Plaintiffs' common law nuisance claims are similarly without merit. First, citing comment e to the RESTATEMENT (SECOND) OF TORTS § 821B, Defendants claim that "conduct proscribed by statute" does not "conclusive[ly]" establish an unreasonable interference with a public right for purposes of a common law nuisance claim.[144] Dist. Opp., p. 11.[145] Notably, the same comment also states as follows:

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[142] *See, e.g., McPherson v. Kelsey*, 125 F.3d 989, 995–96 (6th Cir. 1997) (" '[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived. It is not sufficient for a party to mention a possible argument in the most skeletal way, leaving the court to ... put flesh on its bones.' ") (citation omitted).

[143] 21 C.F.R. § 1301.74 is undeniably a substantive regulation, as it was issued under the statutory authority of the DEA, as delegated to it by the DOJ, and was promulgated after public notice and comment. *See* 21 U.S.C. §§ 821, 871; 28 C.F.R. § 0.100(b); Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 F.R. 7776-7825, 7776, 7785 (1971).

[144] Presumably, Defendants are referring to the following language from comment e: "Subsection (2) has listed three sets of circumstances for determining whether an interference with a public right is unreasonable. They are not conclusive tests controlling the determination of whether an interference with a public right is unreasonable. They are listed in the disjunctive; any one may warrant a holding of unreasonableness. They also do not purport to be exclusive." RESTATEMENT (SECOND) OF TORTS § 821B cmt. e (1979).

[145] Defendants also claim that "where a statute is more general and the alleged violation more technical, a finding of a statutory violation does not conclusively prove *any* element of a common law absolute public nuisance[,]" again citing § 821B cmt. e. Dist. Opp., p. 12. But comment e makes no reference to "technical" violations, and its only reference to a "general statute" does not support this proposition. RESTATEMENT (SECOND) OF TORTS § 821B cmt. e ("If the common law crimes for public nuisance have been supplanted or

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> If, however, *particular conduct is declared to be a public nuisance by a specific statute*, an ordinance, or *an administrative regulation*, the act may provide, or be construed to mean, that the defendant is guilty of the crime even though his interference with the public right was purely accidental and unintentional. Within the constitutional or other limitations upon the power of the legislative body, *these acts are conclusive as to* the existence of the crime and *the unreasonableness of the interference*. *This strict criminal responsibility is carried over to the tort action*.

RESTATEMENT (SECOND) OF TORTS § 821B cmt. e.[146] As discussed above, the specific type of conduct forming the basis of Plaintiffs' nuisance claims has been declared to be a public nuisance by Ohio statute. OHIO REV. CODE § 4729.35. Moreover, the Ohio Supreme Court has "often applied public nuisance law to actions connected to . . . statutory or regulatory violations involving public health and safety." *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002).

Defendants also argue that "[u]nlike statutory violations, mere *regulatory* violations cannot form the basis for liability for an absolute nuisance under Ohio law." Dist. Opp., p. 12 n.44 (emphasis in original). The Ohio Supreme Court has clearly held otherwise with respect to public nuisances. *See Beretta*, 768 N.E.2d at 1142 ("'Unreasonable interference' includes . . . conduct that is contrary to a statute, ordinance, *or regulation* . . . . [W]e have often applied public nuisance law to actions connected to . . . statutory *or regulatory* violations involving public health or safety[.]") (emphasis added) (citation omitted).[147] None of the cases cited by Defendants holds otherwise. In *Szuch v. FirstEnergy Nuclear Operating Co.*, 60 N.E.3d 494 (Ohio App. 6th Dist. 2016), for example, the court merely held that a shooting range owner's violation of certain noise regulations did not categorically establish a *private* absolute nuisance.[148] Defendants' other cases are similarly

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supplemented by a broad general statute, the situation has not been changed in any material respect, and the common law rules are generally still applicable to both criminal and civil liability.").

[146] *See also id.* at cmt. c ("[A]ll of the states have numerous special statutes declaring certain conduct or conditions to be public nuisances because they interfere with the rights of the general public. . . . These statutes amount to a legislative declaration that the conduct proscribed is an unreasonable interference with a public right. Municipal ordinances and administrative orders and regulations may have a similar effect. In these cases there may be no need for a court finding of unreasonableness").

[147] *See also* RESTATEMENT (SECOND) OF TORTS § 821B(2)(b) (unreasonable interference with a public right may be shown by "conduct [that] is proscribed by a statute, ordinance *or administrative regulation*") (emphasis added).

inapposite.[149]

Finally, Defendants assert in conclusory fashion that a CSA violation would not establish "any element" of Plaintiffs' negligence claim because "the Court has already ruled" that "Plaintiffs cannot rely on the doctrine of negligence *per se* to impose liability under the CSA." Dist. Opp., p. 12 (citing Dkt. #1680 and Dkt. #1861-1). First, the Court has made no such ruling with respect to *these* Plaintiffs. The order to which Defendants cite is one in which the Court dismissed certain negligence *per se* claims brought by the Muscogee (Creek) Nation and The Blackfeet Tribe of the Blackfeet Indian Nation (collectively, the "Tribes") *under Montana and Oklahoma law*. Dkt. #1680 at pp. 23-25. The other document to which Defendants cite is not even an order of the Court, but rather Defendants' summary judgment motion on Plaintiffs' negligence *per se* claims. As Plaintiffs explain at length in their Memorandum of Law in Opposition to Distributor Defendants' Motion for Summary Judgment on Plaintiffs' Negligence *Per Se* Claims (Dkt. #2187), incorporated by reference as if fully set forth herein, Plaintiffs have valid negligence *per se* claims in this case.

Regardless, as explained in their motion, for purposes of Plaintiffs' general negligence claims, "the CSA and its implementing regulations provide a standard of care for the underlying common

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[148] Specifically, in *Szuch*, the plaintiff sought a permanent injunction against the owner of a shooting range, claiming, among other things, that owner's violation of certain noise regulations constituted a *private* absolute nuisance. *Id.* at 509. The owner asserted a defense under an Ohio statute that prohibited courts from granting injunctive relief "under an ordinance, resolution, or regulation of a political subdivision, or under the common law of this state against the owner or operator of a shooting range in a nuisance action if the court determines that the owner's or operator's action or omissions that are the subject of a complaint substantially complied with the chief's noise rules or the chief's public safety rules, whichever apply to the nuisance." *Id.* at 500. The court agreed with the owner's argument that the noise regulations were "not required 'safety statutes,' but instead [we]re merely criteria for determining whether a shooting range is entitled to immunity." *Id.* at 509. The court held: "Violation of the noise regulations strips the shooting range of its immunity from nuisance claims, but it does not categorically mean that the shooting range is unlawful. Thus, we find appellants' contention that the FENOC shooting range constitutes a *private*, absolute nuisance to be without merit."

[149] *See Ogle v. Kelly*, 629 N.E.2d 495, 498-99 (Ohio App. 1st Dist. 1993) (holding that a property owner's violation of a local ordinance related to stormwater drainage did not constitute negligence *per se* and thus was not sufficient to establish a *private* absolute nuisance); *Kemp v. Medtronic, Inc.*, 99-3720, 2001 WL 91119, at *1 (6th Cir. Jan. 26, 2001) (holding that "it appear[ed] that under Ohio law, the violation of administrative rules and regulations 'does not constitute *negligence per se*' "; no discussion of nuisance claims) (emphasis added) (quoting *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198, 203 (Ohio 1998) (holding "the violation of an administrative rule does not constitute *negligence per se*"; no discussion of nuisance claims) (emphasis added)).

law duty by establishing how a reasonable manufacturer or distributor of dangerous drugs would and should behave under the circumstances." Ps' Compliance MOL, p. 24 & n.40 (citing cases). Defendants provide no substantive argument refuting this proposition. Nor do they refute whatsoever Plaintiffs' assertions that granting summary judgment would streamline Plaintiffs' conspiracy claims at trial because "this Court has found that the same illegal conduct constituting a statutory public would state a claim for civil conspiracy." *Id.* at pp. 24-25.

C. A Determination that Defendants Violated the CSA Will Streamline the Presentation of Plaintiffs' RICO Claims at Trial.

1. Defendants' Violations of CSA §§ 841 and 843 Constitute Racketeering Activity under the RICO Statute.

Under the RICO statute, "racketeering activity" is explicitly defined to include "any offense involving . . . the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the [CSA]), punishable under any law of the United States[.]" 18 U.S.C. § 1961(1)(D). Defendants' violations of §§ 841 and 843 of the CSA clearly fall within this definition of "racketeering activity."

Under § 841(a), it is "unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance[,]" "[e]xcept as authorized by [Subchapter I of the CSA]. 21 U.S.C. § 841(a). Violators of § 841 are subject to lengthy prison terms, among other penalties. 21 U.S.C. § 841(b). Defendants appear to believe that as long as they were still registered under the CSA and distributed their controlled substances to other registrants, their manufacture and distribution of controlled substances was "authorized" under Subchapter I of the CSA even if it violated other sections of the statute or its implementing regulations. Not so. Indeed, Defendants' interpretation has been rejected by the United States Supreme Court,[150] and is belied by recent

[150] *See U. S. v. Moore*, 423 U.S. 122, 124, 131-32, 134 (1975) (rejecting argument that a registrant cannot be prosecuted under § 841; "We think the statutory language cannot fairly be read to support the view that all activities of registered physicians are exempted from the reach of s 841 simply because of their status."; "[O]nly the lawful acts of registrants are exempted."). Moreover, in analyzing the legislative history of the CSA, the Supreme Court explicitly recognized that: "Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. It was aware that registrants, who have the greatest

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criminal enforcement actions based on CSA violations.[151] As described at length above (*supra* at § II), Defendants manufactured and distributed opioids without maintaining "effective controls against diversion[,]" which is *not* authorized under the CSA. 21 C.F.R. §§ 1301.71(a), 1301.74(b).[152] Section 841 explicitly makes it a crime to manufacture or distribute controlled substances in a manner not authorized by Subchapter I of the CSA. 21 U.S.C. § 841. The CSA's implementing regulations explain the scope of what is authorized under the CSA. Defendants argue that a regulatory violation is not sufficient because "RICO predicate acts of racketeering consist of violations of enumerated *felony* criminal statutes—not administrative rules governing registration." Dist. Opp., p. 15. This argument misses the point: by violating DEA's regulations, Defendants violated 21 U.S.C. § 841, which is inarguably a felony criminal statute. [153] Defendants' cases are distinguishable.[154]

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access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *Id.* at 135.

[151] *See, e.g., United States v. Rattini, et al.,* S.D. Ohio Case No. 1:19-cr-00081-SJD-5, Dkt. No. 7 (July 17, 2019), at pp. 2-14 (U.S. Attorney charged Miami-Luken with violating § 841 because it failed to fulfill the requirement to maintain effective controls to prevent diversion by, specifically, refusing to report suspicious orders; based on indictment's allegations, Miami-Luken and certain individuals were charged with conspiracy to violate the CSA); *United States v. Rochester Drug Co-Operative, Inc.*, S.D.N.Y. Case No. 19-cr-00290, Dkt. No. 2, at 1-22 (U.S. Attorney alleged Rochester Drug violated duty to maintain effective controls against diversion by, specifically, refusing to identify and report suspicious orders (*i.e.* violating § 823 and 21 C.F.R. § 1301.74(b)) as the basis for a felony charge of drug trafficking in violation of § 841; U.S. Attorney also alleged that Rochester Drug misrepresented its due diligence practices and willfully failed to file suspicious order reports, contributing to another criminal charge under § 842(a)(5)).

[152] Subchapter I of the CSA specifically authorizes the Attorney General to promulgate regulations "relating to the registration and control of the manufacture [and] distribution . . . of controlled substances." 21 U.S.C. § 821. The standard dictated to the Attorney General regarding registration includes consideration of Defendants' maintenance of effective controls against diversion as part of the Defendants' registration. 21 U.S.C. § 823(a)(1), (b)(1). Regulations promulgated pursuant to these sections make clear that "[a]ll applicants and registrants *shall* provide effective controls and procedures to guard against theft and diversion of controlled substances" and that the DEA must consider the security controls, including § 1301.74 as the operating procedures, as a necessary part of maintaining effective controls against diversion. 21 C.F.R. 1301.71(a) (emphasis added). This framework makes clear that CSA's Subchapter 1 does, in fact, require Defendants to maintain effective controls against diversion.

[153] *See U.S. v. DeBoer*, 966 F.2d 1066, 1068–69 (6th Cir. 1992) (affirming conviction where "the language in § 841(a)(1) *and 21 C.F.R. § 1306.04(a)* clearly defines the pharmacist's responsibilities that give rise to conduct that constitutes an unlawful distribution of a prescription drug.") (emphasis added); *U.S. v. Vamos*, 797 F.2d 1146, 1151-52 (2d Cir. 1986) ("In order to enable physicians and certain others (e.g. manufacturers) lawfully to distribute or dispense drugs within the course of their professional practice Congress provided that 'Persons registered . . . under this subchapter . . . are authorized [to dispense controlled substances] . . . to

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Defendants also claim that their violations of CSA § 843 do not constitute predicate acts under RICO. Dist. Opp., pp. 16-17. Section 843 makes it unlawful for registrants to "knowingly or intentionally . . . furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II[.]" 21 U.S.C. § 843(a)(4). The bulk of Defendants' argument is simply a reiteration of their position that the CSA and its implementing regulations do not impose a duty to report suspicious orders to the DEA. Dist. Opp., pp. 16-17. As discussed at length above, this argument is without merit. *Supra* at § I. For that reason, *Cal. Architectural Bldg. Prod., Inc. v. Franciscan Ceramics, Inc.,* cited by the Distributors, is inapplicable. 818 F.2d 1466 (9th Cir. 1987). There, the plaintiff used mail and wire fraud as predicate acts, and the court analyzed whether the plaintiff had sufficiently alleged intent to defraud. Noting that the plaintiff was using an omission theory, the court held that the plaintiff could not allege an intent to defraud by omission unless there

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the extent authorized by their registration and in conformity with the other provisions of this subchapter.'. . . The Attorney General, acting under authority granted by the CSA, 21 U.S.C. § 821, promulgated regulations providing that controlled drugs may be prescribed 'for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice[.]' ") (internal citation omitted); *U.S. v. Hayes*, 595 F.2d 258, 259, 261 (5th Cir. 1979) (affirming conviction of registered pharmacist for "conspiracy to distribute Schedule II controlled substances in violation of 21 U.S.C. s 841(a)(1) *and 21 C.F.R. 1306.04(a)* promulgated thereunder"; "The purpose of the regulation is to define the circumstances in which a physician or pharmacist who is registered to dispense controlled substances may nevertheless be held to have violated the proscription against manufacturing, distributing or dispensing a controlled substance contained in 21 U.S.C. s 841."; "When a pharmacist fills a prescription that he knows is not a prescription *within the meaning of the regulations* he is subject to the penalties of s 841.") (emphasis added).

[154] In *U.S. v. Alghazouli*, 517 F.3d 1179 (9th Cir. 2008), which did not involve RICO at all, the court decided whether a regulatory violation satisfied the "contrary to law" requirement in 18 U.S.C. § 545, a statute prohibiting the fraudulent or knowing importation of merchandise "contrary to law[.]" *Id.* at 1182-83. After analyzing the statutory history, the court determined "that Congress intended 'law', *as used in § 545*, to include a regulation only if a statute specifies that the violation of that regulation is a crime." *Id.* at 1187 (emphasis added). Unlike the statutes at issue in *Alghazouli*, CSA §§ 841 and 843 do not criminalize conduct that is "contrary to law," but rather conduct that violates "this subchapter" (*i.e.*, Subchapter I of the CSA and regulations promulgated thereunder). *Brown v. First Tennessee Bank Nat. Ass'n*, 753 F. Supp. 2d 1249 (N.D. Ga. 2009), which did involve RICO, is also inapplicable. First, the *Brown* plaintiff did not allege a felony racketeering act. Instead, he attempted to use mail and wire fraud to enforce a right owed to him under a federal statute. *Id.* at 1253-54, 1260. Second, as the court recognized, the Veteran's Affairs statute at issue in *Brown* was accompanied by an "extensive administrative regime" designed to protect the plaintiff's rights. Here, there is no extensive administrative regime that is intended to protect plaintiff's rights. The holding of *Brown* is not applicable to the facts, or statutory and regulatory structure at issue here.

was "an independent duty" to disclose. 818 F.2d at 1472. Here, § 843 in fact imposes a duty to disclose.

Defendants further argue that violations of § 843(a) do not fall within the enumerated predicate act language set forth in RICO's § 1961(1)(D). But the statutory language clearly says otherwise. RICO's § 1961(1)(D) states that "felonious . . . concealment" related to controlled substances that is "punishable under any law of the United States" constitutes "racketeering activity. 18 U.S.C. § 1961(1)(D). CSA's § 843(a)(4), in turn, makes it unlawful for registrants to "knowingly or intentionally . . . omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II[.]" 21 U.S.C. § 843(a)(4). Defendants acknowledge this statutory language, but claim that "the felonious 'concealment' that is actionable under Section 1961(1)(D) has to do with the controlled substances themselves, not recordkeeping." Dist. Opp., p. 17. They cite no authority for this proposition and provide no further argument supporting their conclusory statement. As such, the argument is inadequately briefed and should be rejected for that reason alone. *See McPherson*, 125 F.3d at 995–96.[155] Moreover, Magistrate Ruiz explicitly rejected *this very same argument* in his Report and Recommendations on Defendants' motions to dismiss. Dkt. #1025 at pp. 45-46.[156]

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[155] Additionally, the text of the CSA and implementing regulations makes clear that Defendants' argument regarding "record keeping" is ludicrous. While 21 U.S.C. 843 refers to finishing false information and/or omitting material information from reports required under the CSA, the reports required are part and parcel of the DEAs authority to "control . . . the manufacturer, distribution, and dispensing of controlled substances." 21 U.S.C. § 821. And, as previously discussed, the requirement of identifying and reporting suspicious orders is one of the "operating procedures necessary to prevent diversion" as part of the requirement that registrants, like Defendants, "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. §§ 1301.71(a), 1301.74. These provisions make clear that the "record keeping" requirement Defendants describe, is actually a necessary part of their authorization to manufacture and distribute as well as necessary to prevent diversion. There is no interpretation of these provisions that does not fall within 18 U.S.C. § 1961(1)(D)'s description of "any offense involving . . . felonious manufacture, importation, receiving, concealment, buying, selling, *or otherwise dealing in controlled substances*." 18 U.S.C. § 1961(1)(D) (emphasis added).

[156] Specifically, Magistrate Ruiz stated: "First, the court is skeptical whether providing false information, as alleged, does not constitute 'concealment' or 'otherwise dealing in a controlled substance' as Distributors suggest. Second, the court takes not that in making the above assertion, the Distributors completely cut out of the provision of § 1961(1)(D) that expressly references 'concealment' of a controlled substance and furnishing false information as alleged may constitute concealment. Thus, the plain language of § 1961(1)(D) does not appear to preclude the use of a violation of § 843(a)(4)(A) as a predicate act. The argument that (footnote continues on next page)

2. Plaintiffs Have Submitted Substantial Evidence that Defendants Knowingly Violated the CSA.

Defendants claim that Plaintiffs "do not even attempt" to show that Defendants "knowingly or intentionally" violated §§ 841 and 843. Dist. Opp., pp. 17-18. This is absurd. The term "knowingly" only requires that Defendants were "conscious and aware" of their actions, "realized what [they were] doing or what was happening around [them]," and "did not [act] or [fail to act] because of ignorance, mistake, or accident." 1A Fed. Jury Prac. & Instr. § 17:04 (6th Ed.); *accord U.S. v. Odom*, 13 F.3d 949, 961 (6th Cir. 1994) ("The jury instruction required the jury to determine that Odom possessed the firearm knowingly, meaning voluntarily and intentionally, and not because of mistake or accident"); *U.S. v. Wheeler*, 349 Fed. Appx. 92, 97 n.1 (6th Cir. 2009) (unpublished).[157] Here, Plaintiffs' arguments regarding the CSA violations are not predicated on inferences, or extrapolation. Rather, they are based on the policies and procedures that the Defendants used as part of their statutorily required obligations to maintain effective controls against diversion. Specifically, as set forth at length in Plaintiffs' Compliance MOL (pp. 26-142), and also above (*supra* at § II), Plaintiffs have provided substantial evidence that Defendants knew their duties under the CSA and its implementing regulations pertaining to suspicious order monitoring and violated those duties by knowingly or intentionally (i) failing to implement SOM systems that would identify suspicious orders, (ii) failing to timely report suspicious orders to DEA, (iii) shipping orders flagged as potentially suspicious without first investigating the order to ensure it was not likely to be diverted, and (v) ignoring a wealth of data readily available to them that would have helped them detect diversion. In fact, many Defendants had prior enforcement actions initiated against them by

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§ 843 is not expressly enumerated as a predicate act by § 1961(1)(D) is untenable, as § 1961(1)(D) does not identify any single, specific section of the United States Code that would constitute a predicate act under the subsection. If Defendants' construction were adopted, the entirety of § 1961(1)(D) would be rendered a nullity." *Id.* at p. 46.

[157] *Cf. Alghazouli*, 517 F.3d at1192–93 (interpreting the term "knowingly" in another statute providing for criminal liability as requiring "only that the defendants knew the facts that constituted the violation"; "[T]he phrase 'knowingly violates' does not necessarily indicate anything more than that the defendant must know what he or she is doing. The phrase does not necessarily indicate that the defendant also must know that what he or she is doing is illegal.").

the DEA for their CSA violations,[158] yet continued to fail to maintain effective controls against diversion.

Another example of their knowledge comes from their attempts to secretly work behind the scenes to undermine the DEA and influence public opinion.[159] For example, through their trade association, Defendants would feed questions for lawmakers to ask during congressional hearings in an attempt to challenge DEA officials. **Ps' Ex. 589** [HDA_MDL_000077967] at *968 (proposing the following question in an attempt to insinuate the DEA has not provided clear regulatory guidance to registrants: "What are you doing [to] help well-intentioned registrants determine who they can do business with?"). A few days later, Congresswoman Blackburn asked a DEA witness the exact question Defendants proposed in a House of Representatives hearing.[160] Defendants also sought to influence lawmakers and legislation directly.[161] As McKesson's Senior Vice President, Ann Berkey, stated with respect that same House of Representatives hearing:

> Per our discussion with Rep. Burgess on Saturday, his office called me this afternoon before the hearing and asked me for questions that he could ask DEA. I shared the point Don had raised about their role as an enforcer and the frustrations this posed to working the agency . . . as well as Mark's query about how to get the DEA to work more collaboratively with distributors. Note the recap below; he followed through . . .!

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158 *See, e.g.,* Ps' Compliance MOL, pp. 27-28, 52, 92-93, 108-110.

159 *See, e.g.,* **Ps' Ex. 586** [ABDCMDL00370752]; **Ps' Ex. 587** [ABDCMDL00371423]; **Ps' Ex. 588** [ABDCMDL00371403].

160 *See* Transcript of 4/7/14 House of Representatives Subcommittee on Health and Committee on Energy and Commerce hearing on "Improving Predictability and Transparency in DEA and FDA Regulation," at p. 45, *available at* https://docs.house.gov/meetings/IF/IF14/20140407/102093/HHRG-113-IF14-Transcript-20140407.pdf.

161 *See, e.g.,* **Ps' Ex. 590** [MCKMDL00652338] (3/1/12 e-mail between HDA, Cardinal, McKesson, and ABDC; "The hearing on prescription drug diversion in the Energy & Commerce Subcommittee on Commerce, Manufacturing and Trade went pretty much as expected. . . . It was very apparent that the preliminary work with the Committee members *was very effective. There were no accusatory attacks*.") (emphasis added); **Ps' Ex. 591** [McKesson-Ganley-017, ABDCMDL00167570]; **Ps' Ex. 592** [MCKMDL00661629]; **Ps' Ex. 593** [WAGMDL00330627]; **Ps' Ex. 588** [ABDCMDL00371403]; **Ps' Ex. 594** [ABDC-Norton-001, WAGMDL00646203]. Similarly, Defendants sought to influence the DEA directly. **Ps' Ex. 595** [ABDCMDL00276562].

Ps' Ex. 596 [MCKMDL00661483] at *484. Similarly, ABDC sought assistance from Senator Feinstein "in encouraging the [DEA] to agree to meet with [ABDC] and move expeditiously in its interactions with [ABDC] regarding the suspension of the DEA registration of [ABDC's] Orlando distribution center[,]" going so far as to draft a form letter for Senator Feinstein to use in her communications with the DEA. **Ps' Ex. 597** [ABDCMDL00398338].

Distributors also acted through their trade association to "turn the tide" of public opinion regarding their role in the opioid epidemic and "inoculate the industry against future flare-ups of the issue[,]" by implementing various "tactics," such as "reframe[ing] the issue" to the media and publicly voicing approval for proposed legislation addressing the epidemic in order "to demonstrate that HDMA and its members are working hand-in-hand with members of Congress to solve the problem." **Ps' Ex. 598** [ABDCMDL00269293] at *294-295. These tactics were necessary, according to their trade association, to avoid risking, among other things, (i) "[t]he credibility and reputation of the industry," (ii) "[m]ore litigation across the country," (iii) "[a]dditional state or federal regulation that could negatively impact HDMA member companies," and (iv) "[p]otential business and financial losses[.]" *Id.* at *293.[162]

Additionally, Cardinal internally discussed petitioning the DEA for a regulation to clarify "suspicious orders" or suspicious order monitoring expectations, noting that the "optics would be positive" for it to ask for clarity and there would be little downside, as it was "[u]nlikely that DEA would create such a regulation[, and] [t]herefore, [there was a] low risk of resulting in something overly restrictive or difficult to follow"—demonstrating that the requests for guidance were not genuine or simply a cover for the industry's failure to comply. **Ps' Ex. 601** [CAH_MDL2804_01530082] at *082.

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[162] *See also* **Ps' Ex. 599** [ABDCMDL00161397] (ABDC internally circulating a list of "[i]ndustry talking points on opioid abuse," prepared by HDA, for use to "try[ ] to head off congressional response like last time if possible"); **Ps' Ex. 600** [McKesson-Ganley-014, MCKMDL00407771] at *774 (HDMA presentation noting that "State efforts to address, reduce, prevent Rx abuse and diversion" was a "[c]hallenge[ ] on [the] [h]orizon").

Defendants put forward no evidence tending to disprove that they acted knowingly. They failed to raise a triable issue of fact regarding their "knowing" behavior in violation of §§ 841 & 843.

3. Plaintiffs Have Not Sought Summary Judgment on the Causation Element of Their RICO Claims.

Plaintiffs' Compliance MOL asserted that the nature and history of Defendants' CSA violations satisfied both the "pattern" and "racketeering activity" elements of Plaintiffs' RICO and OCPA Supply Chain claims. In response, Defendants argue that Plaintiffs have failed to "identify the specific predicate acts that [each Defendant] committed, and prove that those predicate acts were a 'direct' cause of [Plaintiffs'] injury." Dist. Opp., p. 18. Defendants confuse establishing a "pattern of racketeering activity" with establishing causation.[163] These are separate elements of a RICO claim, and Plaintiffs have not moved for summary judgment on causation. That Plaintiffs will be required to establish causation at trial does not prevent this Court from ruling as a matter of law that Defendants' violations of the CSA satisfy establishes both the "pattern" and the "racketeering activity" elements required for Plaintiffs' RICO claims. The cases cited by Defendants are inapposite, as they all dealt with whether a plaintiff's RICO *causation* allegations were sufficient to survive a *motion to dismiss*.[164]

Defendants put forward no argument, facts or law applicable to the *pattern* element.[165] 18 U.S.C. § 1961(5) ("plaintiff must prove at least two acts of racketeering activity . . . "). Plaintiffs

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[163] Plaintiffs clearly have identified numerous predicate acts for each Defendant, as described at length above and in their motion. Ps' Compliance MOL, pp. 26-142; *supra* at § II.

[164] *See Hemi Group, LLC v. City of New York, N.Y.*, 559 U.S. 1, 5, 8 (2010) ("This case arises from a motion to dismiss[.]"; court determined that the plaintiff could not establish the causation requirement of its RICO claim); *Kerrigan v. ViSalus, Inc.*, 112 F. Supp. 3d 580, 608–09 (E.D. Mich. 2015) (finding plaintiffs had "not pleaded the requisite causal connection between their injuries and predicate acts committed by each Defendant," which was necessary to avoid dismissal of their § 1962(c) claim); *Worldspan Marine Inc. v. Comerica Bank*, 18-21924-CIV, 2019 WL 2267262, at *6 (S.D. Fla. Feb. 22, 2019) ("Plaintiffs here have not alleged facts sufficient to show that each Plaintiff suffered an injury was directly caused by any Defendant's conduct."), *report and recommendation adopted,* 18-21924-CIV, 2019 WL 2267258 (S.D. Fla. Mar. 14, 2019).

[165] Lest Defendants argue that Plaintiffs conceded their inapplicable causation arguments, Plaintiffs incorporate, as if fully set forth herein, their (i) Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation, Dkt. #2203, and (ii) Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Plaintiffs' Civil Conspiracy, RICO and OCPA Claims, Dkt. #2196, at pp. 91-98.

need only prove "continuity plus relationships which combines to produce a pattern." *Vild v. Visconsi*, 956 F.2d 560, 565 (6th Cir. 1992). The relationship prong "is satisfied if the predicate acts have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events."[166] "Continuity is both a closed- and open-ended concept, referring either to a closed period of repeated conduct, or to past conduct that by its nature projects into the future with a threat of repetition." *Aces High*, 2019 WL 1531876 at *7 (internal punctuation omitted).

Defendants waived argument regarding the pattern element by choosing, instead to argue inapplicable principles related to causation. But, if the Court chooses to consider Defendants' twisted application of causation to the pattern element, Plaintiffs' proof still satisfies the law. The evidence submitted regarding the Defendants' SOMs violations, each a violation of the CSA, had the same or similar purposes, results, participants, victims, methods of commission, and were related by similar characteristics and were not isolated events. Similarly, Defendants' prolonged violations of the CSA fulfill the continuity requirement by demonstrating repeated conduct that occurred during a closed period, and/or conduct that constitutes a threat of repetition that projects into the future.

D. Although Expert Testimony Is Not Required to Establish Defendants' Breach of Their CSA Duties, Plaintiffs Have Provided Such Testimony.

In their Oppositions, several Defendants claim that Plaintiffs' motion should be denied as to them because they failed to provide expert testimony regarding those Defendants' SOM systems. Dist. Opp., pp. 56, 59, 84-85, 93-94, 102. This claim is both legally and factually incorrect. First, expert testimony is not needed when the breach of duty is so obvious as to be easily recognized by the average juror. Under federal and Ohio law, "it is the accepted rule that expert testimony is not necessary for the proof of negligence in non-technical matters or those of which an ordinary person may be expected to have knowledge, or where the lack of skill or want of care is so obvious as to

[166] *Aces High Coal Sales, Inc. v. Community Bank & Trust of West Georgia*, 2019 WL 1531876, *6 (6th Cir. April 9, 2019). *See also Natural Immunogenics Corp. v. New Port Trial Corp.*, 2016 WL 11520711, *12 (N.D. Cal. Aug. 1, 2016 ("whether the predicate acts alleged are sufficiently related is seldom at issue").

render expert testimony unnecessary." *Evangelista v. Black*, 126 N.E.2d 71, 75 (Ohio. App. 1953). The common-knowledge exception has been applied in numerous instances under federal law and Ohio law.[167] Beyond the federal courts, the Federal Government has recognized that "even to a layman" orders of unusual size can be suspicious, as can orders that deviate from a normal pattern by over 100%. Denial of Application for Registration, Morton Pharm., Inc. 38 Fed. Reg. 9524-02, at 9526 (April 17, 1973). In this case, the evidence demonstrates that Defendants' violations were so prevalent and so egregious that it would be well within the knowledge of this Court, or the jury, to determine Defendants failed to comply with their statutory and regulatory duties under the CSA. For example, a layman can conclude that the failure to identify even one suspicious order during the height of the opioid epidemic, and despite the undisputed facts establishing the existence of suspicious orders, is a failure to have a sufficient SOM system.

The cases cited by Defendants are entirely distinguishable. Dist. Opp., pp. 84-85, 94-95. *Ramage v. C. Ohio Emerg. Serv., Inc.*, 592 N.E.2d 828 (Ohio 1992) simply stands for the proposition that expert testimony is required to establish a breach in the standard of care and proximate cause *in a medical malpractice case*. *Id.* at 833 ("It is well settled in Ohio that in order to prevail in a medical malpractice claim, a plaintiff must demonstrate through expert testimony that, among other things, the treatment provided did not meet the prevailing standard of care.").[168] Moreover, even in *Ramage*, the court recognized that the common knowledge exception is an exception to this general rule. 592 N.E.2d at 103.[169] Defendants' other cases are also inapposite.[170]

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[167] *See e.g. United States v. Elliot*, 876 F.3d 855, 866 (6th Cir. 2017) (finding in a conspiracy to distribute oxycodone case that expert testimony was not necessary where there is "evidence of plainly improper prescribing practices that a lay juror could recognize as illegitimate").

[168] The Sixth Court and courts in this District, when citing *Ramage* for this proposition, have done so in the context of medical malpractice or medical causation. *See, e.g., Est. of Rodriguez v. U.S.*, 722 Fed. Appx. 409, 414 (6th Cir. 2018) (unpublished); *Jackson v. Mowry*, 1:12 CV 3083, 2013 WL 526916, at *6 (N.D. Ohio Feb. 11, 2013).

[169] *See Radous v. Emeritus Corp.*, 1:12-CV-319, 2013 WL 1283903, at *2 (N.D. Ohio Mar. 27, 2013) (Polster, J.) (citing *Ramage*, among other cases, for the proposition that under the "exception, no expert testimony is required in a medical-malpractice claim on the issues of duty and breach when the defendant's lack of care 'is so apparent as to be within the comprehension of laymen, and requires only common knowledge and experience for an understanding of it.' ") (citation omitted).

Regardless, even if expert testimony was required, Plaintiffs have offered it.[171] As the Advisory Committee Notes to Federal Rule of Evidence 702 explicitly acknowledge: "[R]ule [702] accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts." FED. R. EVID. 702, Advisory Committee Notes – 1972 Proposed Rules. Here, Plaintiffs designated Dr. Seth Whitelaw as an expert on the relevant standards surrounding the design, implementation, and operation of corporate and controlled substances compliance programs for the pharmaceutical industry. Whitelaw Rep., Dkt. #2000-26, at 2. Dr. Whitelaw's opinions were not limited to merely the analysis of compliance controls by certain distributors. Dr. Whitelaw set forth an industry-wide standard of care concerning SOM policies.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act (Dkt. #1910-1) and Plaintiffs' Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Dkt. #1924-1), in their entirety.

Dated: August 16, 2019

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[170] *Montgomery v. Gooding, Huffman, Kelly & Becker*, 163 F. Supp. 2d 831, 835 (N.D. Ohio 2001) ("Ohio courts require expert evidence *in a legal malpractice case* to establish the attorney's breach of the duty of care.") (emphasis added); *McNeil Pharm. v. Hawkins*, 686 A.2d 567 (D.C. App. 1996) (noting that "*this jurisdiction* has required expert testimony to explain the applicability of statutes where the statute is relied upon as establishing the standard of care" and it was bound to follow its own precedent) (emphasis added); *Kinn v. HCR Manorcare*, Case No. CI200908520, 2011 Ohio Misc LEXIS 13507, at * (Ohio C.P. Nov. 29, 2011) (denying plaintiff's summary judgment motion; after first finding that plaintiff had provided no evidence that the federal regulations related to hospice care he claimed defendants violated were applicable to the alleged breach at issue, the court noted, citing no legal authority, that even assuming they were, plaintiff needed to present expert testimony in order to establish defendants' breach *of those specific regulations* and that plaintiff's expert had "already opined that he could point to no regulatory violations by [d]efendants").

[171] Contrary to Rite Aid's unsupported claim otherwise (Dist. Opp., p. 85), Plaintiffs' designation of experts to testify regarding certain Defendants' SOM systems is not a concession that expert testimony is mandatory. Expert testimony can be used, even when not required, so long as it is helpful to the trier of fact.

Respectfully submitted,

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